UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

TRACK 1 DEFENDANTS' MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION

[REDACTED VERSION]

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PRELIMINARY STATEMENT

Plaintiffs seek certification of two classes and a subclass of potentially more than 200 million persons and more than 10,000 corporate entities to recover alleged overpayments on 136 different prescription drugs manufactured by five defendant groups over more than a decade.[1] In addition to the sprawling nature of the proposed classes, plaintiffs' motion for class certification rests on a theory of the case that differs dramatically from the theory set forth in their successive amended complaints and briefing on two motions to dismiss. Plaintiffs originally told this Court that AWP literally means an average of actual sales prices. Plaintiffs argued that payors were deceived because published AWPs often greatly exceeded the actual selling prices during the class period and payors were unaware that a spread existed between AWPs and actual selling prices. Because the Court had to assume plaintiffs' allegations were true at the pleading stage, plaintiffs persuaded the Court to allow this case to proceed past the motion to dismiss stage.

Now, in the face of an overwhelming record that refutes their original theory, plaintiffs turn their back on much of what they told the Court in opposing defendants' motions to dismiss. Through their class certification expert, plaintiffs finally concede that AWP is a reimbursement benchmark and that many payors understood that there was a spread between published AWPs and what their expert calls the "average sale price" or ASP.[2] To compensate for this radical shift, plaintiffs advance a new theory that they were defrauded because the precise difference between the published AWPs and their expert's so-called "ASP" exceeded the putative classes' "expectations" as to the size of the spread for hundreds of drugs.

Plaintiffs try to avoid the inherently individual nature of an "expectation"-based claim by suggesting that their experts can construct a "market expectation" that can be used to derive a

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[1] The Track 1 Defendants are: AstraZeneca, the BMS Group, SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, the Johnson & Johnson Group, and the Schering-Plough Group. Each of these defendants is either a group of constituent companies or the product of multiple mergers over the course of the class period.

[2] Declaration of Raymond S. Hartman In Support of Plaintiffs' Motion for Class Certification (hereinafter "Hartman Decl.") ¶ 17 and Attachment D at 1. Defendants do not accept or adopt plaintiffs' definition of "ASP."

"but for" spread from which causation and injury can be established on a class-wide basis. As explained more fully below, there is no single "market expectation" in the complex, competitive environment for pharmaceutical products where the reimbursement amount for drugs is but one of many negotiated and interrelated terms. In fact, the system for pharmaceutical reimbursement is not an "efficient market" like a stock exchange where all buyers pay the same price at any given time and by law are assumed to be making purchasing decisions on the basis of openly available information. Nor is pharmaceutical reimbursement based on form contracts that have been the subject of some class actions. Instead, reimbursement for prescription drugs is based on a web of proprietary contracts that are negotiated individually and competitively among manufacturers, wholesalers, pharmacies, pharmacy benefit managers ("PBMs") and third-party payors. Hence, the drug reimbursement system is inherently unsuited to class certification. The individual issues created by these multi-faceted relationships preclude plaintiffs from satisfying Rule 23 – *even if the proposed classes related to only one defendant and one drug*, much less five defendant groups and 136 drugs, or nearly 20 defendant groups and more than 300 drugs.

First, plaintiffs cannot satisfy the predominance requirement of Rule 23(b)(3) with respect to their proposed Third-Party Payor classes, because individualized factual determinations will be required to establish the essential elements of their RICO, consumer fraud and civil conspiracy claims.[3] Second, plaintiffs cannot establish that common issues of law predominate, because the state law claims of both their proposed Third-Party Payor classes and their proposed Medicare Part B class are governed by the disparate laws of over fifty jurisdictions. Finally, plaintiffs cannot demonstrate that class action treatment is a superior means of litigating their claims. Indeed, plaintiffs' trial plan demonstrates that plaintiffs' claims are incapable of being tried on a class basis. Rather than efficiency and economy, class

[3] The complex market for generic drugs is even less suited to class litigation, as explained in the individual brief of defendant Schering-Plough. Schering's subsidiary, Warrick, is the only manufacturer of generic drugs among the Track 1 Defendants.

certification would create a management nightmare for this Court, far exceeding the burdens this case has already imposed on it.

STATEMENT OF FACTS

I. "AWP" is Simply a Benchmark

As plaintiffs now concede, "AWP" is simply a benchmark sometimes used in connection with reimbursement for brand-name drugs. Contrary to plaintiffs' steadfast denials in their pleadings and in oppositions to motions to dismiss, it has long been understood that published AWPs are not a reflection of actual prices. It appears the term "AWP" may have been the creation of California officials in the late 1960s in connection with the MediCal program. (Declaration of Steven J. Young In Opposition to Plaintiffs' Motion for Class Certification (hereinafter "Young Decl.") ¶ 48 and Ex. 7.) Originally developed to aid in manually adjudicating prescription claims, the term was adopted by the private sector as a benchmark. Throughout the entire class period (and predating it), AWPs for brand-name drugs have generally reflected a mark-up of 20-25% above manufacturers' "Wholesale Acquisition Cost" or, as it is also known, "WAC."

Plaintiffs' industry expert, Dr. Schondelmeyer, acknowledged that going back at least to the early 1980s, he was aware that published AWPs did not reflect actual prices. (Schondelmeyer Tr. 366-68 (WFC Ex. 14).)[4] In fact, twenty years ago the Office of Inspector General ("OIG") issued a report concluding that retail pharmacies in selected states were acquiring pharmaceuticals for on average 15.9 percent less than AWP. (*Medicaid-Limitation on Payment for Drugs, Medicare & Medicaid Guide* (CCH) ¶¶ 34, 157 at 10, 206 (Sept. 1984) (SJY Vol. III.B) (Defs. Motion to Dismiss Ex. 31).) As the report notes, wholesalers contacted by the OIG in 1984 reported that AWP bore no relationship to actual pricing.

[4] For the Court's convenience, the portions of the record cited herein are attached as exhibits to the declarations submitted in support of the Track 1 Defendants' opposition to class certification. Citations to the exhibits attached to these declarations are abbreviated as follows: Declaration of Steven J. Young ("SJY"), Declaration of Eric M. Gaier, Ph.D. ("EMG"); Declaration of Robert P. Navarro ("RPN"), and Declaration of William F. Cavanaugh, Jr. ("WFC").

Indeed, analyses by defendants' economist of the prices paid for prescription drugs and of reimbursement rates confirm that, in many instances, neither bear a relationship to AWP. As discussed below, prices and reimbursement rates are affected by competition, knowledge and the interrelationships among the terms and conditions of contracts between purchasers and sellers. Each of these factors gives rise to individual issues that can only be analyzed on an individual basis. (Declaration of Eric M. Gaier, Ph.D. In Support of the Track 1 Defendants' Opposition to Class Certification (hereinafter "Gaier Decl.") ¶¶ 23, 31-32, 47-49, 60-61.)

II. Discounting and Differential Pricing Are Long-Recognized Practices in the Prescription Drug Business

A. The Degree of Discounting Varies Greatly, Depending on a Purchaser's Bargaining Power

It is useful to think of the pharmaceutical industry in terms of classes of trade, such as pharmacies, hospitals, managed care organizations, physicians and government entities. Manufacturers typically offer different prices to different classes of trade. Furthermore, the prices negotiated by any given purchaser within a class of trade will differ significantly from the prices negotiated by other purchasers within that class of trade. These differences are based on purchasers' ability to influence prescribing decisions as well as structural differences. (Schondelmeyer Tr. 144 (WFC Ex. 14).)

For example, retail pharmacies have little negotiating leverage with manufacturers. They have little influence over the drugs that are prescribed or administered to patients and must stock many kinds of drugs. (Young Decl. ¶ 51.) Retail pharmacies generally acquire brand-name drugs at or around WAC. (Young Decl. ¶ 52.) In contrast, hospitals have long been able to negotiate much better prices than retailers. Hospitals can control which drugs are administered in their facilities through the use of formularies. (Young Decl. ¶ 54.) Plaintiffs' industry expert, Dr. Schondelmeyer, conceded that deep discounting off of AWP to hospitals goes back to the

1970s. (Schondelmeyer Tr. 118-119 (WFC Ex. 14).) Private hospitals were not the only ones to negotiate lower prices than retail pharmacies.[5]

In 1991, eleven years before the initial AWP complaint was filed, plaintiffs' expert, Dr. Schondelmeyer, estimated pricing among the various "classes of trade." He estimated that independent and chain pharmacies, which have little influence over drug selection, were purchasing at approximately AWP minus 13% and 22%, respectively, while groups with significant influence over drug selection, such as long-term care facilities, hospitals and the government, were purchasing at approximately AWP minus 35%, 40%, and 50%, respectively. (*Prescription Drug Study: A Report to the Minnesota Legislature on the Prescription Drug Market*, at 46 (Apr. 1994) Health Economics Program, Minnesota Dep't of Health) (WFC Ex. 2)); (Schondelmeyer Tr. 205-207 (WFC Ex. 14).) As Dr. Schondelmeyer noted in 1992, "the net effect of these discounts, all of which are legitimate, is a wide range in the prices paid by purchasers in retail and institutional settings."[6]

These price differences among various classes of trade were also the subject of widely publicized litigation and legislative battles in the early 1990s among drug companies and retail pharmacies. *See In re Brand-Names Prescription Drug Antitrust Litig.*, 186 F. 3d 781, 787 (7th Cir. 1999) (recognizing that different classes of trade have different market power: "The least elastic demanders are the pharmacies, because they must stock a full range of drugs in order to be able to fill prescriptions"). In these lawsuits, filed more than a decade ago, retail pharmacies cited price differences between what retail pharmacies paid (roughly WAC) and what so-called

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[5] Government hospitals, such as those operated by the Veterans Administration and Department of Defense, by law receive the best prices and discounts available. (Young Decl. ¶ 56.) Physician clinics typically purchase only physician-administered drugs. Their competitive leverage over manufacturers varies widely. The amount of leverage depends on a host of factors, including the degree of discretion the clinic's doctors have as to what drugs to administer. (Young Decl. ¶ 55.)

[6] Frances B. Palumbo, Stephen W. Schondelmeyer, David W. Miller, & Stuart M. Speedie, *Battered Bottom Lines: The Impact of Eroding Pharmaceutical Discounts on Health Care Institutions*, 49 AM. J. HOSP. PHARM. 1177, 1178 (1992) (WFC Ex. 3).

"favored purchasers" paid. These differences reflect "spreads" on certain drugs between WAC and the actual prices paid by favored purchasers from 229% to 19,900%. (*In re Brand-Names* Consolidated Amended Class Action Complaint, at 29 (WFC Ex. 1).)

B. Types of Discounting

Because of intense competition in the pharmaceutical industry, several forms of discounting have evolved. For example, "prompt-pay" discounts, as the name suggests, are offered by manufacturers to wholesalers if payment is made within 30 days. (Schondelmeyer Decl. ¶82.) These are generally about two percent. (Young Decl. ¶ 39.) Due to competition among wholesalers, wholesalers' negligible profit margins in recent years have been devised primarily from the spreads created by these discounts. (Young Decl. ¶ 26.)

Hospitals and other entities that buy at deep discounts often secure those discounts through something known as "chargebacks." Under a chargeback system, wholesaler margins, which are relatively small, remain the same, but the manufacturer is able to negotiate discounts with particular customers. (Young Decl. ¶ 40.)

Manufacturers also provide certain customers with rebates. Rebate amounts are negotiated through individual contracts between manufacturers and entities that can influence prescribing decisions. Manufacturers will enter into rebate agreements both with product purchasers and entities that are responsible for providing reimbursement to the extent they can influence that drug's utilization. Rebates are usually calculated as discounts off of WAC. (Young Decl. ¶ 41.)

III. The Drug Reimbursement System is Based on a Series of Distinct, Arm's Length Negotiated Relationships.

A. Self-Administered Drugs

The vast majority of drugs prescribed by physicians in the United States are self-administered drugs, dispensed to patients through retail and mail order pharmacies as well as through private and governmental hospital and clinic pharmacies. (Young Decl. ¶ 98.) Of the

136 Track 1 defendants' drugs identified in the AMCC, 106 are self-administered drugs. These drugs treat hundreds of different diseases and conditions, and compete in distinct therapeutic markets in which different pricing and marketing strategies may be employed.

1. The Evolution of the Distribution and Reimbursement Systems for Self-Administered Drugs

The profound changes over the past two decades in healthcare insurance have produced a reimbursement system based on a multitude of individually negotiated contracts.

(a) The "Managed Care" Revolution

For decades, most Americans with health insurance had "indemnity" insurance that allowed patients control over the choice of healthcare provider and facility. As a result, insurers had little or no bargaining power over healthcare providers who were paid based on their full, undiscounted charges for the services and products provided. (Young Decl. ¶ 66.)

In response to escalating healthcare costs in the 1980s, insurers began to offer "managed care" policies in which insurers, now known as third-party payors ("TPPs"), offered lower premiums in exchange for members surrendering some degree of choice to the TPP. (Young Decl. ¶¶ 67-69.) TPPs structured their policies to provide incentives for beneficiaries to use certain "approved" physicians and hospitals instead of others. The ability of a TPP to select or exclude healthcare providers from a list of approved providers gave TPPs bargaining power to negotiate lower prices from these providers who competed against one another for access to a TPP's beneficiaries. (Young Decl. ¶ 68.)

Today, over 197 million Americans are members of a health insurance plan, the vast majority of which provide some form of prescription drug coverage. (Young Decl. ¶ 21.) In general, individuals or their employers or unions contract with large insurance companies for medical and prescription drug coverage. (Young Decl. ¶ 61.) Some employees and unions have formed their own benefit fund. Taken collectively these TPPs comprise the putative class. Individuals and employers pay premiums in exchange for the TPP paying for the providers'

services and products. (*Id.*). In turn, TPPs take on the risk that the premiums received will be greater than the cost of reimbursing providers and administering benefits. (*Id.*).

(b) The Revolution Comes to Prescription Drugs

Historically, self-administered drugs have been dispensed largely by retail pharmacies that either bought through wholesalers or directly from manufacturers in the case of retail chains and mail order pharmacies with warehousing capacity. (Young Decl. ¶¶ 28, 30.) Pharmacies would add a "usual and customary" mark-up to the acquisition price of the drug being dispensed to a customer who would pay for the prescription directly and submit a claim to an insurer for reimbursement.[7]

In the 1980s, prescription drug coverage also became a "managed" benefit. TPPs began to negotiate reimbursement contracts with pharmacies, just as they had negotiated with physicians and hospitals. The strategy was to extract lower reimbursement rates from retail pharmacies by including (or excluding) pharmacies from a TPP's network. (Young Decl. ¶ 68.) Offsetting a TPP's ability to deny a pharmacy access to its plan beneficiaries was the need to create and maintain adequate retail networks. This led to arm's length negotiations over reimbursement rates. (Young Decl. ¶¶ 129-132).

Since 1991, there has been significant evolution in the coverage for pharmacy-dispensed drugs. In 1990, 63% of retail customers were paying the pharmacy's full cash price for prescription drugs. By 2002, cash paying customers dropped to 14% of the total retail customers, with the remaining 86% covered under Medicaid or commercial insurance. Today, virtually all of the commercial insurance coverage is through the managed care model, whereby pharmacy reimbursement is defined by contractual relationships with TPPs or their designated representatives. (Young Decl. ¶¶ 75-76, 208.)

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[7] Kenneth W. Schafermeyer, Stephen W. Schondelmeyer, & Joseph Thomas, III, *An Assessment of Chain Pharmacies' Costs of Dispensing a Third Party Prescription*, at 5 (May 1990) (WFC Ex. 4).

TPPs did not stop with pharmacy dispensing costs in their efforts to control drug costs. TPPs developed formularies, lists of approved drugs for which TPPs would agree to provide drug coverage. TPPs began to recognize that, among other things, their power to create and enforce formularies of approved drugs could be used to extract discounts and rebates from drug manufacturers. Drug manufacturers and TPPs began to enter into contracts in which TPPs would secure negotiated prices in exchange for formulary inclusion and other benefits. (Young Decl. ¶¶ 110-11.) The negotiated price often had a rebate component to it in which a TPP would earn a rebate if it demonstrated that it could influence the market share of a manufacturer's product. (Young Decl. ¶ 112.)

(c) The Role of Pharmacy Benefit Managers

Offering and administering a drug benefit is a complex and risky endeavor. To this day, large TPPs continue to manage their drug benefit, including the negotiations with retail pharmacy networks and drug manufacturers described above. Some TPPs, however, sought to contract out the benefit. In response, PBMs began to emerge. (Declaration of Robert P. Navarro In Support of Track 1 Defendants' Opposition to Class Certification (hereinafter, "Navarro Decl.") ¶¶ 17-23.) Initially handling claims processing for mail order and health plans with in-house pharmacies, over time PBMs expanded the bundle of services they could provide TPPs. (Schondelmeyer Tr. 111-12, 125-27 (WFC Ex. 14).) Among other things, many PBMs negotiated and contracted with thousands of pharmacies to create pharmacy networks that were marketed to TPPs that choose not to have their own networks.

Generally speaking, TPPs may contract with PBMs for (a) administrative services, (b) network creation and management, (c) drug cost control functions, or (d) a risk assumption function. From a TPP's perspective, these all are functions it may perform internally or delegate to the PBM, depending on the cost and benefits of doing so. (Young Decl. ¶ 116); (Schondelmeyer Tr. 123-24 (WFC Ex. 14).)

Throughout the 1990s, there was significant expansion in the number of TPPs that elected to utilize the services of a PBM to gain economies of scale and purchasing power. For example, in 1999, 90% of HMOs contracted with PBMs while fewer than 37% did so in 1994. Today, approximately 95% of all patients with drug coverage receive benefits through a PBM that has contracted with a commercial or government-sponsored plan. (Young Decl. ¶ 104.)

PBMs aggressively compete against one another for this TPP business, as the Federal Trade Commission has found on at least three occasions in recent years. (Navarro Decl. ¶ 58); (Correspondence from FTC to Assembly Member Greg Aghazaian, at 5-6, (Sept. 7, 2004) (RPN Ex. 51) (describing PBM competition as "vigorous").)

Plaintiffs claim that PBMs contracted with manufacturers to earn "secret rebates" that PBMs did not share with TPPs. The fact that PBMs were able to extract discounts and rebates from manufacturers has never been a secret. According to plaintiffs' expert, the idea came from TPPs. (Schondelmeyer Tr. 120 (WFC Ex. 14) ("[T]hird-party payors began to ask the PBMs: Can you help us manage the cost of prescription drugs. . . . Can you negotiate discounts or rebates with pharmaceutical manufacturers.").)

Moreover, many TPPs, such as Aetna and Anthem, have continued to operate their own PBMs. (Navarro Decl. ¶ 17.) These TPPs, which are among the largest putative class members, have entered into the very type of agreements plaintiffs now challenge. Plaintiffs have done no comparison of the terms defendants have negotiated with alleged co-conspirators, the stand-alone PBMs, and with PBMs owned and operated by TPPs. (Schondelmeyer Tr. 280-81 (WFC Ex. 14); (Hartman Tr. 240-41 (WFC Ex. 10).) Plaintiffs' industry expert, Dr. Schondelmeyer, is of the opinion that to the extent TPPs have entered into similar rebate contracts with manufacturers as stand-alone PBMs, they are fellow conspirators and their interests are at odds with other TPP class members. (Schondelmeyer Tr. 254-56 (WFC Ex. 14).)

2. Contracts under Managed Care

The gradual adoption of the managed care model throughout the 1980s and 1990s required hundreds of TPPs to negotiate individual contracts with hundreds of thousands of physicians and pharmacies (or PBMs, which in turn contracted with pharmacies). With no established industry standards, TPPs, providers, pharmacies and PBMs entered into a wide range of contractual relationships that varied depending on the parties' subjective reimbursement objectives and relative negotiating positions.

(a) Contracts between TPPs and Pharmacies

In negotiating reimbursement for self-administered drugs with networks of pharmacies, TPPs simply sought to reimburse pharmacies at the lowest available market price.

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Gradually over the decade, the retail margin that pharmacies earned was reduced through the competitive contractual negotiations. As a general matter, the margin pharmacies earn on the distribution of self-administered drugs is thin. (Young Decl. ¶ 96.) Nevertheless, the margin has not been eliminated entirely. TPPs never intended to eliminate that margin through their reimbursement contracts. Moreover, because of inadequate dispensing fees, the margin pharmacists made on acquisition costs has long been a recognized cross-subsidy. (Stephen W.

Schondelmeyer, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices,* at 7, (June 21, 2004) (WFC Ex. 5)); (Stephen W. Schondelmeyer, *Pharmacy Compensation and Reimbursement*, in THE APHA PHARMACY COMMISSION ON THIRD PARTY PROGRAMS FINAL REPORT 68 (1986) (WFC Ex. 6)); (Young Decl. ¶ 132.)

(b) Contracts between TPPs and PBMs

TPPs usually select a PBM through a competitive bidding process whereby PBMs submit responses to TPP's requests for proposals ("RFPs") that define elements of the proposed engagement.[8] (Navarro Decl. ¶ 59.) Typically, PBMs compete on non-price and price dimensions. (*Id.* ¶ 60.) For example, plaintiffs make much of a supposed lack of transparency provided by PBMs concerning their rebating and reporting functions. This is an example of a non-price dimension that is subject to negotiation.

The negotiation of the bundle of services and consideration exchanged by the TPPs and PBMs often involves a trade-off between the amount of drug reimbursement and other forms of consideration afforded. Indeed, a comparison of the bids submitted by PBMs in response to an RFP shows the trade-off between the bundles of services proffered and contemplated consideration. (Young Decl. ¶ 122); (Navarro Decl. ¶ 59.) A comparison of various PBM contracts awarded shows that the contracted reimbursement rates vary by contract with the total bundle of contracted services covered by the agreement. (Navarro Decl. ¶¶ 60-62.)

As the discovery record has revealed, the contractual relationship between TPPs and PBMs can take many forms depending on a TPP's strategic desires and the arm's length negotiations for the bundle of services a PBM can provide. For example, a TPP may wish to place the entire reimbursement risk on the PBM. At the other end of the spectrum, a TPP may

[8] As one PBM has noted, "[c]ustomers will routinely pit bidders against one another by letting one bidder know that another has better financial terms or that one bidder is proposing a better package of services, and will negotiate the most favorable terms and service levels possible." (Gilson Decl. ¶ 11 (RPN Ex. D).)

simply contract with a PBM to provide administrative services in exchange for a fee. (Navarro Decl. ¶¶ 25-27, 41-42.)

How a particular TPP and PBM deal with rebates that a PBM, acting on behalf of itself or one or more TPPs, may negotiate with a manufacturer is a function of their contractual negotiations. TPPs have been free through arm's length negotiations to demand pass-through or sharing of rebate dollars and to retain the right to audit rebate information. In fact, such arrangements are common. (Navarro Decl. ¶¶ 41, 43-44.)

Accordingly, as one PBM official has stated, "[a]s a result of the customer specific negotiation process and the fact that each customer's choice of services and programs results in a unique overall package, the basis for the actual cost of the customer's prescription drug program can only be determined by examining the customer's contract." (Gilson Decl. ¶ 21 (RPN Ex. D).).

(c) Contracts between PBMs/TPPs and drug manufacturers

As noted previously, manufacturers negotiate rebate contracts with TPPs directly or through PBMs acting as the TPP's intermediaries. The terms of those negotiated contracts depend on the relative bargaining power of the PBM or TPP and a drug manufacturer. Most rebate contracts between a PBM and a manufacturer are expressed in terms of WAC, not AWP. (Navarro Decl. ¶ 74.)

There is also wide variation in the methodologies employed to pay manufacturer rebates to PBMs (and to health plans through their PBMs), including flat rebates and various types of market share rebates. Moreover, a PBM and a manufacturer may negotiate different methods of calculating the rebates for different drugs as well as different rebate percentages for different drugs. (Navarro Decl. ¶ 75 and supporting exhibits.) As a result, health plans that deal with a manufacturer through the same PBM often have their rebates calculated in different ways. (Navarro Decl. ¶ 76.)

B. Physician-Administered Drugs

Drugs that physicians administer to patients comprise a limited subset of prescription drugs. The AMCC identifies 15 such drugs sold by Track 1 Defendants. Manufacturers sell physician-administered drugs to wholesalers, which distribute them to the doctors, hospitals, and other healthcare settings in which those drugs are administered, or directly to those entities. (Young Decl. ¶¶ 29, 140.)

1. Reimbursement for Physician-Administered Drugs

The reimbursement channels for physician-administered drugs are similar to the reimbursement channels for self-administered drugs in one important respect: both are governed by myriad privately negotiated contracts between parties with variable leverage and competing motivations. Otherwise, the two systems are significantly different.

For patients who have health insurance, private insurers reimburse doctors for the services and pharmaceuticals they provide to those patients. Because the terms under which doctors are reimbursed for drugs and services are privately negotiated in a competitive marketplace, the terms of those reimbursements vary widely. (Young D ecl. ¶¶ 141-42.) The wide variation of reimbursement terms is caused by several factors, including: (1) the bundle of services sought by the TPPs, (2) the geography and market share served by doctors and TPPs, and (3) the doctor's specialty and the level of competition among others in that specialty. Regarding doctors' purchase of drugs, several additional factors come into play, such as (1) the type of practice; and (2) the discounts the doctors receive. (Young Decl. ¶¶ 145, 148-49.)

TPPs contract directly with physician groups. PBMs generally play no role in the process. Many TPPs enter into reimbursement agreements with physicians and physician groups that are silent with respect to the methodology for reimbursing prescription drugs because the parties are negotiating a bundle of services, of which drugs is a small part. Of those TPP agreements that specify a reimbursement methodology, often that methodology (e.g., capitation) is not expressed as a percentage of AWP. (Young Decl. ¶ 141.) In limited instances, TPPs enter

into contracts with physicians and physician groups that express negotiated reimbursements as a percentage of AWP. (Young Decl. ¶ 142.)

TPPs deposed in this matter testified that they understood that AWP did not represent actual drug costs, but rather was a benchmark used to express the reimbursement negotiated between the parties, and they intended the physicians to earn a margin on drugs dispensed to their members. TPPs also testified that disclosures concerning drug costs would not have altered the negotiated reimbursement. Others explained that acquisition costs were irrelevant to their reimbursement decisions. (Young Decl. ¶ 134); (SJY Ex. 1m.)

Even where the ultimate agreement makes reference to AWP, the amount actually reimbursed to physicians is usually the lesser of (a) an amount listed on the physician "fee schedule" or other limitations, including the "usual and customary" amounts and (b) the physicians' "charged" or "billed" amount. The fee schedule specifies the "maximum" reimbursement amount the TPPs will reimburse the physician for drugs. As a consequence of the individualized negotiations, a TPP may have a different fee schedule for each contracted physician group. (Young Decl. ¶ 143.)

An analysis of the transaction level reimbursement data shows that the amount of reimbursement actually paid pursuant to contracts with physicians varies significantly. (Gaier Decl. ¶ 24.) This variability reflects the results of individual negotiations with parties with different leverage and objectives. The reimbursement data also shows that a significant volume of transactions do not occur at a constant relationship to AWP. (Gaier Decl. ¶¶ 66-76.) Moreover, during negotiations, physician groups routinely contend that servicing fees are inadequate to cover the costs of administering drugs. (Young Decl. ¶ 147.)

2. Reimbursement for Drugs Administered in Hospitals

Plaintiffs' expert concedes that in-house administration of drugs is not within the scope of this case. (Schondelmeyer Tr. 315 (WFC Ex. 14).) Hospitals are not reimbursed based on AWP. Some hospitals are reimbursed a flat rate for each day the patient is in the hospital, other

hospitals are reimbursed a negotiated fee for each unique diagnosis, and yet other hospitals are reimbursed on discounts off of the hospitals' charges. (Young Decl. ¶ 54.)

3. Medicare Part B Reimbursement

Medicare Part B covers all physician-administered drugs that are furnished incidentally to a physician's professional services, 42 U.S.C. §§ 1395k(a) & 1395x(s)(2)(A), as well as certain self-administered drugs employed in connection with chemotherapy treatment.

While plaintiffs now concede that everyone understood that AWP did not reflect actual prices, plaintiffs still apparently contend that, in the Medicare Part B context, the term AWP has a literal definition of actual average wholesale prices. (Hartman Decl. ¶¶ 30(e) & n.48; 33(b).) There is no definition in the relevant statute or regulations. Moreover, as discussed *supra* at section I, the United States government has long understood that AWP did not represent the average of actual acquisition costs. No fewer than three OIG Reports over the past 20 years have confirmed the government's recognition that AWP has simply served as a reimbursement benchmark and has not been synonymous with acquisition costs. (Young Decl. ¶¶ 164-65.)

It also has long been recognized that the AWP reimbursement formulas used by the government provided a cross-subsidy for inadequate service fees. In June of 1991, HCFA proposed that the Medicare Carriers (the private Health Plans that contract with the government to administer the program) should base payment for drugs at 85% of the AWP of the drug. (Young Decl. ¶ 162.) Shortly thereafter, in November 1991, HCFA received comments from physicians indicating that the 85% reimbursement standard was inadequate because it failed to recognize that the drug reimbursement was a subsidy, compensation for Medicare's failure to provide sufficient reimbursement for their professional fees or to cover overhead costs, such as inventory, waste, and spoilage. (*Id.*)

In 1992,[9] after those comments were submitted, HCFA issued a regulation that set the maximum reimbursement under Medicare Part B at the lesser of (1) the estimated acquisition cost ("EAC") as determined by surveys or (2) 100% of AWP. If there was any ambiguity regarding the use of "AWP", in November 1992, the Office of Inspector General of the Health and Human Services (HCFA's parent) clarified that "AWP is not a reliable indicator of the cost of a drug to physicians." (*Id.* at ¶ 163.)

In 1997, Congress set the reimbursement for drugs under Medicare Part B at the lower of the actual billed charges or 95% of AWP. Congress did not include a definition of AWP in the statute, but the legislative history reveals that Congress understood that reimbursement on AWPs had resulted in Medicare reimbursements to physicians for drugs far in excess of their acquisition costs. The history references an OIG report, for example, which stated "Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." (*Id.* at ¶ 165.) [10]

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[9] From 1991 to 1997, Medicare Part B reimbursements for brand-name drugs were based on the lesser of 80% of (1) estimated acquisition costs, which was intended to allow for physician overhead costs, such as inventory, waste, and spoilage or (2) 100% of a drug's AWP. *See* Medicare Program: Payment for Drugs That Are Not Paid on a Cost or Prospective Payment Basis, 42 C.F.R. § 405.517(b) (1992); Medicare Program: Payment for Drugs That Are Not Paid on a Cost or Prospective Payment Basis, 56 Fed. Reg. 59,502, 59,621 (Nov. 25, 1991) (to be codified at 42 C.F.R. § 405.517(b)); 42 U.S.C. § 1395l(o). However, the estimated acquisition cost was never implemented. Instead, Medicare reimbursed covered drugs at the lower of submitted charges or AWP. *See* Medicare Program: Payment Reform for Part B Drugs, 68 Fed. Reg. 50,428 (Aug. 20, 2003) (Proposed Rule). The remaining 20% co-payment is owed by the patient. However, from 1998 to 2003, Medicare Part B reimbursements for brand-name drugs changed to the lesser of 80% of (1) the physician's actual charge, or (2) 95% of the drug's AWP. *See* 42 C.F.R. § 405.517 (1998).

[10] Moreover, although plaintiffs assert the need for class certification because of individuals who made co-pays under Part B, the vast majority of Medicare beneficiaries (over 90% in 1995 and over 87% in 1999) have some form of insurance that supplements their Medicare coverage. (National Health Policy Forum Issue Brief No. 782, *Medigap: Prevalence, Premiums, and Opportunities for Reform* (Sept. 9, 2002) (SJY Vol. III.B).) As a result, a TPP (or Medicaid) primarily paid the 20% co-insurance that Medicare does not pay.

ARGUMENT

I. The Legal Standards for Class Certification

Plaintiffs bear the burden of demonstrating that the criteria set forth in Federal Rule of Civil Procedure 23 have been met. *See, e.g.*, *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613-15 (1997); *Makuc v. American Honda Motor Co., Inc.*, 835 F.2d 389, 394 (1st Cir. 1987). First, plaintiffs must establish all four of the threshold requirements of Rule 23(a). *See* Fed. R. Civ. P. 23(a). In addition, plaintiffs must demonstrate that certification of their proposed classes is appropriate under the more demanding requirements of Rule 23(b)(3), which requires that "questions of law or fact common to the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3); *Amchem*, 521 U.S. at 614.[11] Class actions may not be certified lightly, and a court must conduct a "rigorous analysis" of whether *all* of the prerequisites for class certification have been satisfied. *General Tel. Co. v. Falcon*, 457 U.S. 147, 160-61 (1982).

To decide whether class certification is appropriate, this Court must examine "the claims, defenses, relevant facts, and applicable substantive law" and then consider how a trial on the merits would be conducted. *Castano v. American Tobacco Co.*, 84 F.3d 734, 744 (5th Cir. 1996); *accord Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 295 (1st Cir. 2000) (citing *Castano*). In doing so, the Court cannot rely on plaintiffs' allegations, but, instead, must probe beyond the pleadings in order to "formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate...." *Waste Mgmt.*, 208 F.3d at 298. If significant elements of a claim or defense require individualized proof from each class member, class certification is inappropriate. *See Amchem*, 521 U.S. at 624.

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[11] Although plaintiffs sought certification of a Rule 23(b)(2) declaratory judgment class in their complaint, *see* AMCC ¶ 603, plaintiffs' present motion only seeks certification of Rule 23(b)(3) classes. Accordingly, defendants do not address the many reasons why a Rule 23(b)(2) class could not be certified in this case.

Indeed, the First Circuit has made clear that the district court should "test disputed premises early on if and when the class action would be proper on one premise but not another." *Tardiff v. Knox County*, 365 F.3d 1, at 4-5 (1st Cir. 2004); *see also Gariety v. Grant Thornton LLP,* 368 F.3d 356, 365 (4th Cir. 2004) (holding that district court's reliance on plaintiff's assertions did not satisfy requirement that it conduct a rigorous analysis of Rule 23 requirements). In other words, "similarity of [class members'] claims and situations must be demonstrated rather than assumed." *Szabo v. Bridgeport Machines, Inc.*, 249 F.3d 672, 677 (7th Cir. 2001) (citing *Falcon*, 457 U.S. at 160). In this case, a rigorous analysis of plaintiffs' claims leads to the inescapable conclusion that they are not susceptible to class treatment, particularly in light of the massively large and widely disparate class plaintiffs seek to represent and the host of individualized inquires that would be necessary in order to ensure fairness in the litigation.

Plaintiffs are flat wrong in asserting that they can try their claims with respect to all 136 drugs manufactured by the Track 1 Defendants as a single class-wide action. Indeed, this Court has previously advised plaintiffs that they should not seek to certify "some massive thing I couldn't begin to control or manage. Each company is different. Each one may have different practices." (March 8, 2004, Tr. 10-11.) Defendants anticipate – as often happens in briefing on class certification – that plaintiffs will attempt to overcome the obvious infirmities of their current motion on reply by proposing individual classes composed of the payors for each drug at issue. But such an alteration would achieve nothing; even a single class composed of all the payors for a single one of the 136 drugs at issue would flunk the predominance and manageability tests for the reasons discussed below.

II. Plaintiffs' Proposed Third-Party Payor Classes Fail to Satisfy the Predominance Requirement of Rule 23(b)(3)

As noted above, the Court must consider the nature of proof required to establish the elements of plaintiffs' claims on behalf of each class member, as well as the defenses to which particular plaintiffs and class members may be subject, in order to determine whether Rule

23(b)(3)'s predominance requirement has been met. *See, e.g.*, *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 469 (1978); *Castano*, 84 F.3d at 744. Here, plaintiffs seek to certify the proposed Third-Party Payor classes with respect to their RICO claim, their state law consumer protection claims and their common law civil conspiracy claims, all of which require proof of some sort of deceptive statement, proximate cause and injury.[12] In their motion for class certification, plaintiffs completely ignore critical differences among plaintiffs and members of the proposed class that raise numerous and substantial individual issues with respect to these key elements of their claims. These individual issues far outweigh any superficial commonality among the class members' claims.[13]

A. Plaintiffs Cannot Establish that AWPs were Fraudulent or Misleading on a Class-Wide Basis

As stated above, each of plaintiffs' claims requires proof of a deceptive or misleading statement. Plaintiffs argue that they can establish this element of their claims by focusing on defendants' conduct exclusively.[14] However, plaintiffs' theory of *why* published AWPs are

[12] *See* AMCC ¶¶ 670-73 (alleging mail and wire fraud as predicate RICO acts); *System Mgmt., Inc. v. Loiselle*, 303 F.3d 100, 104 (1st Cir. 2002) (holding that a civil RICO plaintiff must show both 'but-for' and proximate causation to establish a RICO claim); Appendix A (Parts 1 & 2) (summarizing state consumer protection statutes); AMCC ¶ 729 (alleging common law of fraud as underlying tort supporting civil conspiracy claim); *Santiago v. Sherwin Williams Co.*, 3 F.3d 546, 552 (1st Cir. 1993) (holding that civil conspiracy claims require a showing of proximate cause and injury).

[13] As discussed *infra*, at III.A & at n.47, individual issues also predominate for the Third-Party Payor classes with respect to plaintiffs' state law consumer protection and civil conspiracy claims because the disparate laws of over fifty jurisdictions must be applied. *See also* Defendant GlaxoSmithKline's Individual Memorandum in Opposition to Class Certification, in which the Track 1 Defendants join.

[14] Even if this were true, which it is not, a separate inquiry would still be required for each defendant, each drug and potentially each NDC. As the Court noted at the March 8, 2004 pre-trial conference when it suggested that a multi-defendant class might not be appropriate, pharmaceutical manufacturers utilize widely varying pricing, discounting, and marketing practices for their various products. *See* March 8, 2004, Tr. 10-11, 29; *see also* Individual Track 1 Defendant Memoranda. Plaintiffs ignored the Court's guidance on this point and lumped all Track 1 Defendants together in one class relating to all 136 Track 1 drugs. Even assuming plaintiffs can establish that the published AWP for a single one of the products manufactured by a defendant was fraudulently inflated, that proof is irrelevant with respect to the other drugs at issue for that defendant and any other defendant. *See, e.g.*, *Sloan v. C.C. Collings & Co.*, Civ. No. 85-3315, 1986 U.S. Dist. LEXIS 21632 at *2-3 (E.D. Pa. Aug. 12, 1986) (denying class certification) ("Any inquiry into alleged excessive prices charged by the defendants must proceed on an individual basis for each municipal security purchased by each proposed class member at each specific point in time."). Indeed, plaintiffs themselves have acknowledged that their fraud claims could not be resolved without more

misleading has changed dramatically since the inception of this action with significant effects on their ability to prove this element of their claims on a class-wide basis.

Although plaintiffs originally argued that AWPs were false and misleading because they did not equal actual averages of wholesale prices as the plain language of the term might suggest,[15] plaintiffs abandoned that theory in the face of discovery demonstrating widespread knowledge that published AWPs exceeded acquisition costs. In fact, plaintiffs concede that many payors knew that a spread existed between published AWPs and what their expert calls "average sales price" or "ASP." (Hartman Decl. ¶ 10(b) (stating that the payor community has expected AWP to be "larger than ASP by *a reasonably predictable amount*." (emphasis in original).) As a result, plaintiffs now argue that published AWPs were misleading because they were inaccurate "signals" to the marketplace of what plaintiffs' expert calls "ASP." (Hartman Decl. ¶ 11(e).) In other words, plaintiffs argue that published AWPs are misleading because the actual spread between published AWPs and what their expert calls the "average sales price" or "ASP" exceeded plaintiffs' and class members' "expectations" regarding the size of the spread. (*Id.*)

Expectations are inherently subjective. Each plaintiff's and putative class member's knowledge regarding the spreads between published AWPs and actual selling prices is directly relevant to whether published AWPs were deceptive or fraudulent. *See, e.g.*, *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 747 (3d Cir. 1996) (dismissing federal RICO count because "no fraudulent act occurred" where plaintiff acknowledged it was aware defendant was

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than one hundred separate drug-by-drug inquiries. *See* Pls. Opp'n to Amgen's Motion to Dismiss AMCC, at 5 (filed Aug. 9, 2004) ("Whether or not a given AWP is reliable or inflated by the scheme is discovered on a drug-by-drug basis."). Accordingly, plaintiffs' reliance on *In re Synthroid Mktg. Litig.*, 188 F.R.D. 237 (N.D. Ill. 1999), which involved claims against a *single defendant* with allegations relating to just *one pharmaceutical drug*, is misplaced. *See id.*, at 295.

[15] *See* Pl. Mem. in Opp'n to Motion to Dismiss the AMCC, at 45 (filed Sept. 15, 2003) (arguing that defendants' alleged deception was the failure "to disclose that the published AWPs do not reflect the true average wholesale price of the drugs they sell."); Pl. Mem. in Opp'n to Motion to Dismiss the MCC, at 14 (filed Dec. 5, 2002 (arguing that AWP should be "a real average of real prices.").

not complying with terms of contract, which was the basis for plaintiff's mail and wire fraud claim).[16] Even plaintiffs' expert concedes that determining what information a class member has, as well as what its expectations are with respect to the difference between AWP and average selling price, requires an individual inquiry. (Hartman Tr. 95-100, 187-88, 189, 203-05, 261-62, 333-37 (WFC Ex. 10).) As a result, to determine each defendant's liability for each drug at issue, the Court would not only be required to engage in separate fact-finding for each class member to determine what mark-up each class member "expected" each published AWP represented, the Court would also be obligated to evaluate the reasonableness of each class member's beliefs in order to determine whether each class member was defrauded.[17]

Discovery conducted to date demonstrates that the necessity of individual inquiry into each class member's knowledge is not merely a theoretical exercise. Some putative class members, primarily the proposed class representatives, claim that they did not know about a spread between published AWPs and actual selling prices. (Young Decl. Ex. 1e) (listing examples of testimony).)[18] Other putative class members, however, and even some of the named plaintiffs themselves understood that there was a spread between published AWPs and the

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[16] *See also Reynolds v. East Dyer Dev. Co.*, 882 F.2d 1249, 1253 (7th Cir. 1989); *see also Allen Neurosurgical Assocs., Inc. v. Lehigh Valley Health Network*, No. Civ. 99-4653, 2001 WL 41143, at *4 & n.3 (E.D. Pa. Jan. 18, 2001); *Zekman v. Direct Am. Marketers, Inc.*, 695 N.E.2d 853, 861-62 (Ill. 1998); *South Bay Chevrolet v. General Motors Acceptance Corp.*, 85 Cal. Rptr. 2d 301, 312 (Ct. App. 1999).

[17] Variations in class member's knowledge also raises individual issues as to whether the applicable statutes of limitations should be tolled on the grounds of fraudulent concealment. As the First Circuit noted in *Waste Mgmt.*, 208 F.3d at 296, "a necessity for individualized statute-of-limitations determinations invariably weighs against class certification under Rule 23(b)(3)." Such an individualized determination is required here, because plaintiffs' claims involve a wide array of applicable statutes of limitation. *See Rotella v. Wood*, 528 U.S. 549 (2000) (holding that four-year RICO statute of limitations begins to run for each plaintiff when that plaintiff discovered or should have discovered its injuries); Appendix A (Part 1). (summarizing statutes of limitation from over fifty jurisdictions and variations in tolling and accrual rules); *see also O'Connor v. Boeing N. Am., Inc.*, 197 F.R.D. 404, 414 (C.D. Cal. 2000) (decertifying class in light of the need for individual statute of limitations determinations).

[18] Some third-party payors have testified that they thought they were reimbursing pharmacies and providers at actual costs

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average price charged to pharmacies and other providers.

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(SJY Ex. 1b (listing examples of testimony)); (Ecklund Tr. 40 (SJY Vol. II.A) (TCBW 30(b)(6) witness testified that he knew that AWP was "higher than the actual price that a pharmacy of a healthcare provider paid for a drug").)[21] Many putative class members (including those covering roughly 25% of persons with private insurance in the United States) purchased drugs themselves and, therefore, had first hand knowledge of the acquisition costs for drugs and were familiar with the extent and variability of the "spread." (Young Decl. ¶ 153, Ex. 6a.) Still other putative class members have stated that they were not defrauded by published AWPs[22] and would have paid the same prices even if they used a different pricing benchmark than AWP.[23] (SJY Decl. Ex. 1d) (listing examples).)

Moreover, discovery has demonstrated that many class members used benefit consultants, third party administrators, negotiating groups, or other sophisticated intermediaries in the course of their negotiations with PBMs and providers. (Young Decl. ¶ 205; Brecht Tr. 127-28, 156-58 (stating that Man-U relied upon Segal, a benefit consultant, and H4C, a pharmaceutical benefits purchasing cooperative, to negotiate its contract with its PBM (SJY Vol. II.A)) CI REDACTED

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CONFIDENTIAL INFORMATION REDACTED These third parties, who have substantial experience negotiating with PBMs and other providers, were fully aware that a sometimes substantial spread existed between published AWPs and average sales prices. (Young Decl. ¶ 133.) CONFIDENTIAL INFORMATION REDACTED[24] Under the law of agency, the knowledge of these consultants is imputed to the putative class members who utilized their services. *See, e.g.*, Restatement (Second) of Agency §§ 272, 276. Accordingly, the Court will be required to engage in individualized fact-finding regarding each class member's use of such consultants and the imputation of the consultant's knowledge to that class member.

Courts routinely decline to certify classes under similar circumstances. As a number of courts have noted, where a key element to liability involves the actual knowledge of each class member at the time of the transaction in dispute, individual issues predominate and preclude certification. *See, e.g., Zimmerman v. Bell*, 800 F.2d 386, 390 (4th Cir. 1986) (affirming denial of shareholders' certification motion in case involving claim of directors' failure to disclose material facts, where "the extent of knowledge of the omitted facts or reliance on misrepresented facts will vary from shareholder to shareholder").[25] The same conclusion is compelled here.

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[24] The following plaintiffs employed Segal as a benefits consultant: Man-U (Jackson Tr. 14-15, 37-38 (WFC Ex. 11)), PFTHW (Steinberg Tr. 385-86 (SJY Vol. II.A)), TCBW (Ecklund Tr. 84, 162-67 (SJY Vol. II.A)), and UFCW (Ryan Tr. 59, 62 (SJY Vol. II.A)). CONFIDENTIAL INFORMATION REDACTED CONFIDENTIAL INFORMATION REDACTED

[25] *See also In re Ford Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 222 (E.D. La. 1998) (concluding that plaintiffs' fraud claim was inappropriate for certification where "various plaintiffs are in different positions with respect to their actual or constructive knowledge"); *Wilcox Develop. Co. v. First Interstate Bank of Oregon*, 97 F.R.D. 440, 447 (D. Or. 1983) ("Class certification is improper when knowledge of individual class members requires separate adjudications"); *Lewis Tree Service, Inc. v. Lucent Techs. Inc.*, No. 99 Civ. 8556, 2002 WL 31619022 at *7 (S.D.N.Y. Nov. 20, 2002) (declining to certify claim under state consumer fraud statute where liability turned on "the knowledge and sophistication of purchasers" and other individualized factors); *Simer v. Rios*, 661 F.2d 655, 673 (7th Cir. 1981) (concluding that certification was improper where liability turned on proof of

B. Plaintiffs Cannot Establish Causation or Injury on a Class-Wide Basis

Causation is a critical element to each of plaintiffs' claims. *See Poulos v. Caesars World, Inc.* 379 F.3d 654, 664 (9th Cir. 2004) ("Causation lies at the heart of a civil RICO claim. Lumping claims together in a class action does not diminish or dilute this requirement.").[26] Where, as here, proof of causation requires individualized inquiry, class certification is not appropriate. *See, e.g., Poulos*, 379 F.3d at 664-66; *Markarian v. Connecticut Mut. Life Ins. Co.*, 202 F.R.D. 60, 69 (D. Mass. 2001). As one court has explained, "[a]lthough several courts have noted that variations in the *amount* of damages do not preclude certification, this conclusion does not obviate the need for plaintiffs to establish the *fact* of damages when class-wide injury cannot be presumed and forms an essential element of their case." *Lester v. Percudani*, 217 F.R.D. 345, 352 (M.D. Pa. 2003) (emphasis added) (citing *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 188 (3d Cir. 2001)). "That [plaintiffs and class members] were allegedly defrauded in a similar manner does not establish common injury." *Id.*[27]

Plaintiffs argue, based on the "expectations" theory articulated by their expert, that causation and injury can be established with evidence common to the class based on standard economic principles and analysis. *See* Pl. Mem. at 32-35. This analysis is both incorrect and inadmissible.[28] In fact, the opposite is true. In order to determine whether any divergence between actual spreads and class members' expectations regarding the spread caused injury to

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knowledge). Although plaintiffs rely on *Klay v. Humana, Inc.*, No. 02-16333, 2004 WL 1938845 (11th Cir. Sept. 1, 2004), it is impossible to extrapolate from *Klay* that individual inquiry into class member knowledge is not necessary here, given the record cited above.

[26] *Accord Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992); *Camelio v. American Federation*, 137 F.3d 666, 669-70 (1st Cir. 1998) (holding that proof of proximate cause is required under RICO).

[27] *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656 (7th Cir. 2004) is inapposite. *Carnegie* does not stand for the proposition that *all* RICO mail and wire fraud claims are appropriate for class treatment regardless of the individual issues implicated by questions of causation, injury, and damages. Indeed, unlike here, the *only* argument made against certification in that case was the massive size of the class. *See id.* at 660-61.

[28] *See* Track 1 Defendants' Memorandum in Support of Motion to Strike the Declaration of Raymond S. Hartman.

members of the class, the Court will be required to evaluate a number of highly individualized factual issues for each class member, including: (1) as discussed above, each class member's knowledge regarding the spread between published AWPs and actual selling prices; (2) the nature of each third-party payor's contractual relationships with PBMs and providers and the individualized negotiations that led to those relationships; and (3) each third-party payor's reasons for using AWP to express reimbursement levels. (Gaier Decl. ¶¶ 47-59.) Contrary to plaintiffs' sweeping oversimplification of the causation and injury analysis, it is only after conducting these factual analyses on a payor-by-payor basis that this Court will be able to determine whether defendants' alleged conduct actually caused injury to any class member.[29]

1. Individual Issues Relating to Knowledge Preclude Class-Wide Determination of Causation and Injury

Plaintiffs' and putative class members' knowledge regarding AWP is directly pertinent to the issue of causation and injury. *See, e.g., Sandwich Chef of Texas, Inc. v. Reliance Nat'l Indemnity Ins. Co.*, 319 F.3d 205, 218-19 (5th Cir. 2003) ("Knowledge of the truth defeats a claim of fraud because it eliminates the deceit as the 'but for' cause of the damages").[30] Indeed,

[29] Plaintiffs inappropriately rely on several cases for the proposition that individualized questions need not preclude class certification. *See* Pl. Mem. at 26-28. There were no individualized issues of causation in *Waste Mgmt.*, 208 F.3d at 292, because the defendant's re-statement of its financials constituted a *de facto* breach of each class member's contract under Illinois law. Similarly, in *Smilow v. Southwestern Bell Mobile Sys. Inc.*, 323 F.3d 32, 42 (1st Cir. 2003), the court noted: "The common factual basis is found in the terms of the contract, which are identical for all class members. [] The case turns on interpretation of the form contract, executed by all members and defendant." Here, in contrast, the contracts that are central to plaintiffs' class definition are highly individualized and heavily negotiated raising a myriad of plaintiff-specific issues which go directly to the key elements of plaintiffs' claims, including causation. *See* discussion *infra* at II.B.2. In *Klay*, 2004 U.S. App. LEXIS 18494, the RICO class members all had a direct contractual relationship with the HMO defendants. The existence of a number of intermediaries in this case necessarily raises individualized issues of causation, injury and damages that the *Klay* court did not encounter.

[30] *See also Summit Props. Inc. v. Hoechst Celanese Corp.*, 214 F.3d 556, 561 n. 19 (5th Cir. 2000) ("If the relevant decision makers knew the limitations of the product but would have bought it anyway . . . , the fraud would not have been a 'but-for' cause of the plaintiffs' damages."); *Ideal Dairy Farms,* 90 F.3d at 746-47 (affirming dismissal of a RICO fraud claim because of plaintiff's knowledge of the truth); *Reynolds*, 882 F.2d at 1253 ("[A] person who discovers the truth may not claim that a defendant's misrepresentation or omission of information harmed him."); *Oliveira v. Amoco Oil Co.*, 776 N.E.2d 151, 163-64 (Ill. 2002) (holding that, although Illinois's consumer protection statute did not require reliance, plaintiff could not prove causation if he was not deceived by the alleged representations).

in a number of RICO and other fraud cases, courts have found that individual issues with respect to putative class members' knowledge preclude a finding that common issues predominate because such knowledge is a critical fact with respect to causation. *See, e.g., Markarian,* 202 F.R.D. at 69 (refusing to certify class because individual issues of causation predominate where "total mix of information" available to each class member was "distinctive, if not unique" and because "question of causation must be decided with regard to each purchaser in the context of the particular information" purchaser had).[31] This is true even where reliance is not a necessary element of the claim. *See, e.g.*, *Markarian*, 202 F.R.D. at 69; *Lester*, 217 F.R.D. at 352-53; *cf. Loiselle*, 303 F.3d at 104 (holding that proximate cause is a necessary element of a RICO claim even though reliance is not). [32]

As discussed above, discovery in this case demonstrates that knowledge regarding the spread between published AWPs and actual selling prices varies among the putative class members, precluding class-wise determination of a single "expectation" regarding the appropriate spread. *See discussion supra* at II.A. Because individualized fact-finding with respect to each class member's understanding of AWP would be required in order to establish

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[31] *See also Wall v. Merrill Lynch, Pierce, Fenner & Smith*, No. 92-C-16421, 1992 WL 245540, at *3-4 (N.D. Ill. Sept. 21, 1992) (refusing to certify RICO class alleging fraud with respect to market values listed on monthly statements because individual issues regarding causation and reliance predominated where some class members knew true market values independent of what was reported on account statement).

[32] Plaintiffs repeatedly emphasize that reliance is not an element of a RICO claim predicated on mail and wire fraud in the First Circuit. In *Loiselle*, however, the First Circuit explicitly noted that RICO requires proof of "but for" and proximate cause and that "[r]eliance is doubtless the most obvious way in which fraud can cause harm." 303 F.3d at 104. Indeed, the circuits are currently split on whether reliance is a necessary element of a civil RICO claim predicated on the mail and wire fraud statutes. *See Poulos,* 379 F.3d at 666 n.3 (discussing circuit split). To the extent that *Loiselle* holds that proof of reliance is *never* required to establish causation in a civil RICO claim, defendants believe that the case was wrongly decided. Regardless, plaintiffs' state law claims will require many class members to prove reliance. *See* Appendix A (Parts 1 & 2) and B (Parts 1 & 2); *see also* Defendant GlaxoSmithKline's Individual Mem. In Opp'n to Class Cert, *see supra* Note 13. Courts have repeatedly held that a class should not be certified when individual reliance will be at issue. *See, e.g., Waste Mgmt.*, 189 F.R.D. at 198 (citing *Castano*, 84 F.3d at 745).

causation and injury under plaintiffs' "expectations" theory, class treatment is not appropriate. (Gaier Decl. ¶ 53.)[33]

2. Individualized Negotiations Between Class Members and PBMs/Providers Preclude Class-Wide Determination of Causation and Injury

Plaintiffs and their expert also argue that causation and injury can be established on a class-wide basis simply because "reimbursement rates of all or substantially all End Payor Class members were formulaically related to AWP." *See* Pl. Mem. at 33 (citing Hartman Decl. ¶ 24). This deceptively simple formulation entirely ignores that the contracts that are central to plaintiffs' definition of their proposed classes are subject to heavy negotiation and are highly individualized. This fact raises a plethora of individual issues that make this case particularly ill-suited to class treatment, especially where the defendants did not have any contact with many of the putative plaintiffs.

The pharmacy benefit management industry in the United States is a highly competitive industry, and third-party payors typically select their PBMs through a competitive bidding process. *See* FTC-DOJ, *Improving Health Care: A Dose of Competition,* Ch. 7 at 15 ("FTC-DOJ

[33] The antitrust cases on which plaintiffs rely are inapposite. *See, e.g.*, Pl. Mem. at 3, n.5 and accompanying text. In those cases, the plaintiffs claimed that the *actual* prices of specific drugs were raised as the result either of a horizontal conspiracy among competing manufacturers, or single-firm conduct to limit competition – neither of which is alleged here. Indeed, in those cases, the "violation" price was alleged to be measurable against an *objective* "but for" benchmark. Here, of course, the benchmark offered is entirely dependent on the plaintiffs' individual thought processes and complicated by their individualized contractual negotiations. If anything, this case is considerably more like indirect purchaser pharmaceutical antitrust class actions, in which class certification is often denied, because the proof of the causal connection between the defendants' alleged conduct and the claimed harm depends on transactional circumstances unique to putative class members. *See In re Brand-Name Prescription Drug Antitrust Litigation,* No. 94 C 897, 1994 U.S. Dist. LEXIS 16658 (N.D. Ill. Nov. 18, 1994) (whether alleged overcharges were passed through pharmacies to retail purchaser plaintiffs could not be determined on a class-wide basis because pharmacy pricing to customers varied based on individualized factors; certification of indirect purchaser class denied); *Karofsky v. Abbott Labs.*, No. CV-95-1009, 1997 Me. Super. LEXIS 316 (Me. Sup. Ct. Oct. 15 1997) (same); *Kerr v. Abbott Labs.*, No. 96-002837, 1997 WL 314419 (Minn. Dist. Ct. Feb. 19, 1997) (same); *cf. Sample v. Monsanto Co.*, 218 F.R.D. 644 (E.D. Mo. 2003) (denying certification of class of indirect purchasers of genetically modified seeds). *Goda v. Abbott Labs.*, No. Civ. A. 01445-96, 1997 WL 156541, 1997-1 Trade Cases ¶ 71,730, (D.C. Super. Feb. 3, 1997), cited by plainitffs, is clearly distinguishable because District of Columbia law, unlike federal law and that of the states, explicitly provides that a class action plaintiff need not establish fact of injury and the amount of damages for each member of the class. *See* D.C. Code § 28-4508(c) (2001).

Study") (SJY Vol. III.B); (Young Decl. ¶ 121) (noting that PBMs are usually selected through a competitive bidding process).[34] Moreover, each third-party payor has its own unique needs and concerns, and relationships between third-party payors and PBMs reflect those needs and concerns. As a result, PBM services reflect trade-offs and negotiations between the PBM and payor. (Navarro Decl. ¶ 53.)[35] These putative class members thus stand on far different footing than class members in securities fraud cases, or consumer fraud cases premised on uniform contract terms or sales pitches that are not subject to negotiation. (Gaier Decl. ¶ 49.) The payments at issue in this case were the result of highly individualized negotiations between third-party payors and PBMs. As a result, individual issues predominate with respect to causation and proof of injury. *See Robinson v. Texas Auto. Dealers Ass'n,* No. 03-40691, 2004 WL 2222287 (5th Cir. Oct. 5, 2004).

In *Robinson*, the plaintiffs asserted that the defendant automobile dealers unlawfully inflated the price of automobiles by imposing a vehicle inventory tax ("VIT") as a separate item on each sales contract. *Robinson*, 2004 WL 2222287 at * 1. In reversing the district court's certification of a class of purchasers, the Fifth Circuit reasoned that:

> Plaintiffs assume that the VIT represents an additional charge that artificially increases the final purchase price for every consumer in the class. Under plaintiffs' theory, if the charge did not exist, the consumer would pay that much less, or at least some amount less. [ ] Such an assumption defies the realities of the

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Regarding PBM competition, *see also* Correspondence from FTC Office of Policy Planning, Bureau of Competition, and Bureau of Economics to Assembly Member Greg Aghazaian, at 5-6 (Sept. 7, 2004) (RPN Ex. 51) (describing PBM competition as "vigorous"); Navarro Decl. Section IV (PBM industry has been and continues to be "competitive" and "cost-sensitive");

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> haggling that ensues in the American market when one buys a vehicle. Although some purchasers certainly negotiate a price that excludes taxes, titles, and fees, others negotiate with an eye to the 'bottom line.' Bottom-line purchasers base their negotiations on the final purchase price, including every tax, fee, and surcharge. [ ] To determine whether a purchaser negotiated in a top-line or bottom-line fashion, a court would have to hear evidence regarding each purported class member and his transaction. Such an individual examination would destroy any alleged predominance present in the proposed class.

Id. at *4 (emphasis omitted); *see also Lester,* 217 F.R.D. at 352-53 (holding that, "[a]though the fraudulent acts themselves may be common to the proposed class, issues of causation and proof of damages mandate the conclusion that individual issues will predominate" with respect to plaintiffs' RICO and state consumer fraud claims because class members engaged in individualized negotiations).[36]

Negotiations between third-party payors and PBMs are not only individualized but also highly complex, because they involve varying bundles of products and services, not a single fungible product. (Navarro Decl. ¶ 53.)[37] First, a number of pricing components are involved in any contract (*e.g.*, reimbursement rate for brand-name drugs, reimbursement rate for generic drugs, mail order drug pricing, pharmacy dispensing fee, administrative fee, and rebates passed

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[36] *See also Exhaust Unlimited, Inc. v. Cintas Corp.*, No. 02-CV-0614, 2004 U.S. Dist. LEXIS 15153, *24 - 25 (S.D. Ill. July 26, 2004) (denying certification of purported class of purchasers of textile linen supplies and/or services, in part because "prices and other contract terms may be individually negotiated and cover both the total invoice price and each component of that price. . . . Consequently, the result is a diverse mix of base prices and ancillary charges and of products and services, with total invoice prices varying from customer to customer."); *Cohn v. Massachusetts Mut. Life Ins. Co.*, 189 F.R.D. 209, 213 (D. Conn. 1999) (denying class certification of purported class who purchased "vanishing premium" life insurance policies because these policies were individually negotiated and "[t]he lack of uniformity in the thousands of face-to-face transactions at issue ensures the predominance of individual issues"); *Nagel v. ADM Investor Servs.*, 65 F. Supp. 2d 740, 746 (N.D. Ill. 1999), *aff'd*, 217 F.3d 436 (7th Cir. 2000) (denying certification of purported class of farmers who entered into "hedge-to-arrive" contracts with grain merchants and related parties, in part because some merchants negotiated terms individually with each farmer and, as a result, individualized issues predominated); *cf. Buckhalter Travel Agency v. MacFarms Int'l, Inc.*, 141 F.R.D. 144, 154 (N.D. Cal. 1991) (denying class certification in an action against macadamia-nut manufacturers because the differences in the macadamia-nut industry served to create more individual issues than common: "there are significant differences between the markets for macadamia nuts on Hawaii and on the mainland, between large and small purchasers, and between bulk and retail purchasers. In these different markets, defendants price nuts in different ways and purchasers have varying degrees of leverage over defendants.").

[37] *See Mulder v. PCS Health Sys.*, 216 F.R.D. 307, 314-16 (D.N.J. 2003) (denying class certification in ERISA case against PBM for lack of commonality because PBM services and fees differed markedly from plan to plan rendering the PBM's relationship with each of its customers unique).

through to the third-party payor). (*Id.*)[38] These components are interrelated, and a third-party payor's decision to accept a particular bundle of pricing terms is highly idiosyncratic. *See, e.g.* FTC-DOJ Study, ch. 7 at 16-17 (SJY Vol. III.B) (noting that some plans place greater emphasis on paying lower administrative fees as a trade-off for allowing PBMs to keep rebates); (Navarro Decl. ¶¶ 54-62); (Gaier Decl. ¶¶ 60-65).

Second, third-party payors' negotiations with PBMs also involve an array of non-price dimensions (such as plan design – *e.g.*, administrative services versus full service, formulary design, extent of pharmacy network, mail order component, utilization reviews, *etc.*). CONFIDENTIAL INFORMATION REDACTED The bundle of services ultimately selected by a third-party payor is a highly idiosyncratic choice. In evaluating PBM proposals, third-party payors consider the entire package of services offered and the overall pricing structure proposed in light of their specific needs and utilization trends. (Navarro Decl. ¶¶ 53-56); (Gaier Decl. ¶ 61.)[39]

The multi-faceted nature of these relationships between third-party payors and PBMs is significant because the contractual relationships ultimately negotiated by payors and PBMs/physicians embody a number of considerations unique to the particular payor, as well as numerous factors other than AWPs that potentially influence the payor's decision. As a result, isolating a causal link between a single aspect of the contractual relationship – *e.g.*, drug reimbursement formula – and defendants' alleged conduct is difficult and contractually specific. And, because the significance of the reimbursement component of these contracts varies from

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[39] Indeed, even in antitrust cases, courts refuse to certify a class where, as here, plaintiffs' claims involve a complex bundle of services or products that raises individual issues with respect to impact. *See Kennett Corp. v. Massachusetts Furniture & Piano Movers Ass'n, Inc.*, 101 F.R.D. 313, 316 (D. Mass. 1984) (denying certification because the case involved a bundle of moving services that differed from mover to mover and from customer to customer). Similarly, courts have refused to certify classes where the prices paid by class members were influenced by a variety of individualized considerations, in addition to the allegedly inflated price. *See, e.g., In re Beef Indus. Antitrust Litig.*, 710 F.2d 216, 219-220 (5th Cir. 1983); *In re Beef Indus. Antitrust Litig.*, M.D.L. No. 248, 1986 U.S. Dist. LEXIS 24731 (S.D. Tex. June 3, 1986); *American Custom Homes, Inc. v. Detroit Lumberman's Ass'n*, 91 F.R.D. 548, 550 (E.D. Mich. 1981).

payor to payor, causation and injury can only be evaluated on a class member-by-class member basis. *See Markarian*, 202 F.R.D. at 69 ("Contrary to plaintiff's suggestion, unsupported by any relevant, reported case law, it is not appropriate for the court to presume that an alleged omission was so significant as to have proximately caused a prospective purchaser to buy a policy from the defendant."); *see also Piggly Wiggly Clarksville, Inc. v. Interstate Brands Corp.*, 215 F.R.D. 523, 531 (E.D. Tex. 2003) (holding that a class should not be certified if "it will be impossible to present evidence in a common manner as to the price each Plaintiff would have paid but for the alleged conspiracy.") *aff'd*, 2004 WL 1245275 (5th Cir. June 7, 2004).

In affirming the district court's denial of class certification in part because individual issues of causation predominated, the Fifth Circuit in *Sandwich Chef*, explained:

> These RICO fraud cases must be tried individually. [Plaintiffs] are entitled to prove at trial that the insurers with whom they contracted to provide workers' compensation insurance defrauded them . . . by charging premiums that exceeded approved rates. But defendants are equally entitled to defend themselves by offering, for example, evidence that an individual plaintiff, directly or through a broker, negotiated a premium that varied from the filed rate, was aware that the insurer was charging more than what regulators had approved, and therefore was not a victim of fraud.

319 F.3d at 224.

The same principles apply here: although plaintiffs assert that class members were defrauded in a similar manner, the mere existence of a contract that uses AWP to express a negotiated reimbursement level cannot establish that the publication of AWP in pricing compendia proximately caused injury to the entire class.

3. Individual Issues Relating to Plaintiffs' and Class Members' Reasons for Using AWP to Express Reimbursement Levels Preclude a Class-Wide Determination of Causation and Injury

Contrary to plaintiffs' allegations, discovery has shown that a number of major third-party payors in the proposed class did not use AWP as a way to approximate acquisition costs. (Young Decl. ¶¶ 87-92.) Instead, these third-party payors attempted to negotiate the lowest reimbursement rate possible without consideration or focus on the acquisition costs of the

pharmacy or physician. (*Id.*)[40] Indeed, large insurance companies that are putative members of the proposed class CONFIDENTIAL INFORMATION REDACTED have testified that they considered acquisition costs, and the difference between AWP and acquisition costs, to be irrelevant to their reimbursement decisions. (*Id.* and SJY Ex. 1m.)[41] Such companies simply expressed the negotiated reimbursement amount as a discount off of AWP, because such benchmarks allow health plans to manage millions of transactions by providing a reimbursement standard across thousands of pharmacies. (Young Decl. ¶ 49); (Navarro Decl. ¶ 46.) As several third-party payors have testified in this matter, the reimbursement amount they set would not have been different if expressed in terms of another benchmark other than AWP. (SJY Ex. 1d.)

Where, as here, plaintiffs and class members had a variety of reasons for using published AWPs, individualized inquiry with respect to the causal connection between the allegedly fraudulent published AWPs and each plaintiff's and class member's alleged injury is required. *See, e.g., Ruffu v. Johnson & Johnson*, 181 F.R.D. 341, 343-44 (E.D. Tex. 1998) (denying certification of RICO claim because individual issues predominated with respect to causation where consumers may have purchased product for a variety of reasons other than defendants' conduct).[42] Indeed, the fact that plaintiffs and putative class members have continued to utilize AWP as a reimbursement benchmark – even after they admittedly were on notice of the

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[42] *See also Cullen v. Whitman Med. Corp.*, 188 F.R.D. 226, 233 (E.D. Pa. 1999) (finding that individual issues of causation predominate with respect to RICO claim alleging that misrepresentations caused plaintiffs to attend defendant's school); *Caro v. Procter & Gamble Co.*, 22 Cal. Rptr. 2d 419, 433 (Ct. App. 1993) (refusing to certify consumer fraud class where claims depended upon "personal assumptions about the nature of the products [class members] wanted to buy").

allegedly fraudulent nature of published AWPs – strongly suggests the absence of any causal link between the purportedly fraudulent AWPs and any injury alleged by plaintiffs.[43]

4. Plaintiffs Cannot Establish Causation or Injury on a Class-Wide Basis Using Economic Theories and Models

Plaintiffs have submitted the declaration of Raymond S. Hartman ("Hartman"), an economist, to support their contention that causation can be demonstrated on a class-wide basis. Hartman proposes a "formulaic methodology" that allegedly would enable him to compare actual spreads (the difference between the reported AWP and what he calls "average sale price" or "ASP") to "but-for" spread (the difference between the AWPs that would be reported in the absence of the alleged fraud and ASPs). According to Hartman: "If the actual spread exceeds the but-for spread, I can conclude that the AWP scheme led to reimbursement in excess of those [sic] reasonably expected by the market." (Hartman Decl. ¶ 20.)

Hartman proposes to determine his "but-for" AWPs by calculating "yardsticks . . . for market expectations regarding the non-fraudulent relationship between AWP and ASP for groups of drugs and market entities." (Hartman Decl. ¶ 31.) He states that he will calculate these yardsticks by using "industry-wide survey information" that will capture "the average of the market understanding of the difference between AWP, WAC and ASP." (Hartman Decl. ¶ 21); (Hartman Tr. 373 (WFC Ex. 10).) He also states that he intends to calculate "but-for" AWPs by using "actual AWP and ASP data from those manufacturers and their drugs known to be unaffected by the AWP scheme," but he has not identified any such manufacturers or drugs at this point. (Hartman Decl. ¶ 21); (Hartman Tr. 159-60 (WFC Ex. 10).)

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Plaintiff PFTHW continues to utilize AWP in its contract with its PBM and has made no effort to change that contract. (Steinberg Tr. 415-16 (SJY Vol. II. A).) Notwithstanding the fact that THWF has been a named plaintiff in this action since 2002, THWF entered into a new contract with its PBM as late as 2004, and that contract still uses AWP as a reimbursement benchmark with similar discounts off AWP. (Einhorn Tr. 214-18 (SJY Vol. II. A).)

Hartman's use of "expectation yardsticks" is fatal to his theory that causation can be demonstrated on a class-wide basis. As noted above, expectations are inherently subjective and individualistic. Using averages is simply a way of assuming those individual issues away. Reliance on average expectations, as Hartman proposes, obscures important individual issues that bear on liability, causation and injury. (Gaier Decl. ¶ 49.)

Even if Hartman's survey approach were acceptable, Hartman admits that he will need to ask individual questions of more than a dozen class members in order to determine what their "expectations" were. (Hartman Tr. 333-37, 343, 348 (WFC Ex. 10).) He also states that he plans to look at claims data for 300 to 400 class members, and that it will be necessary to look at their contracts and helpful to talk to them about their data. (*Id.* at 238-41.) And when that process is through, Hartman still does not have any idea of how he will deal with class members who do not believe (1) that AWP has any consistent relationship with actual selling prices; (2) that the prices they pay would be any different if a benchmark other than AWP were used; or (3) that they have been defrauded – other than to concede that he would need to talk to these people in order to understand their thinking. (Hartman Tr. 231-34, 366-72, 422-24 (WFC Ex. 10).) Hartman concedes that some class members could suffer no injury. (Hartman Tr. 101, 268-70, 271, 287, 442-43 (WFC Ex. 10).)

Aside from the patent flaws in his methodology – which we address in a separate motion – Hartman's testimony demonstrates that individual issues predominate. There will be no way to avoid discovery and direct and cross examination of countless class members in order to determine causation. This will result in a mini-trial for every class member who participates in that process, and the testimony of those class members who participate will tell the jury nothing about the knowledge and experience of those class members who do not.

At bottom, Hartman's theory that he can determine class-wide impact by reference to an average industry expectation that he assumes informed every reimbursement negotiation is nothing more than a "fraud-on-the-market" theory. However, the "fraud-on-the-market" theory

has been recognized only in fraud cases involving highly efficient markets such as the securities market in which hundreds of millions of trades of a particular commodity occur daily.[44] *See Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1363-64 (11th Cir. 2002); *accord Appletree Square Ltd. P'ship v. W.R. Grace & Co.*, 29 F.3d 1283, 1287 (8th Cir. 1994); *Chavin v. McKelvey*, 25 F. Supp. 2d 231, 237 (S.D.N.Y 1998) (noting that courts in the Second Circuit have limited the application of the "fraud-on-the-market theory" to publicly offered securities in developed, efficient markets).[45] Indeed, "[n]o court has accepted the use of [the fraud-on-the-market] theory outside of the context of securities fraud." *Summit Props.*, 214 F.3d at 561 (rejecting "fraud-on-the-market theory" in RICO action).

Unlike securities markets, the pharmaceuticals market is not an efficient, impersonal trading market, but is instead dominated by thousands of individually negotiated transactions. (Gaier Decl. ¶ 49.) Even plaintiffs' expert concedes that the market in this case is not an efficient market. (Hartman Tr. 115 (WFC Ex. 10).) Indeed, he testified that there are "innumerable" markets in this case and the industry is "complicated." (*Id.* at 117.) For these reasons, plaintiffs cannot take advantage of a "fraud-on-the-market" theory for demonstrating causation. Individual inquiry will be required rendering class certification inappropriate.

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[44] Because the stock market is efficient, the theory assumes that the price of a security is an adequate reflection of its worth and that any false information about the security, if material, is likely to affect the price of the security. Russell Robinson, *Fraud-on-the-Market Theory and Thinly-Traded Securities Under Rule 10b-5: How Does a Court Decide if a Stock Market is Efficient*, 25 WAKE FOREST L. REV. 223, 224 (1990). Accordingly, any individual who purchases the security at a price that is inflated by reason of a misrepresentation or omission of material information is, by definition, injured, regardless of the circumstances of the sale itself. *See, e.g.*, *Lester*, 217 F.R.D. at 352 (discussing fraud on the market doctrine).

[45] *See also In re Livent Noteholders Sec. Litig.*, 211 F.R.D. 219 , 221 (S.D.N.Y 2002) (denying class certification in case involving market for unsecured notes and holding that "the 'fraud-on-the-market' theory will only apply where the market concerned is an efficient one"); *In re Ribozyme Pharms., Inc. Sec. Litig.*, 119 F. Supp. 2d 1156, 1164 (D. Colo. 2000) ("In order to take advantage of the [fraud on the market] doctrine, however, a plaintiff must plead, and ultimately prove, that the market on which the security is traded is efficient").

III. Plaintiffs' Proposed Part B Class Fails to Satisfy the Requirements of Rule 23

A. Common Issues of Law Do Not Predominate Because Plaintiffs' State Law Claims Are Governed by the Disparate Laws of over Fifty Jurisdictions

Significantly, the only claims asserted on behalf of plaintiffs' proposed Medicare Part B class are state consumer protection act claims.[46] As many courts have recognized, "[s]tate consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules." *In re Bridgestone/Firestone, Inc., Tires Prods. Liab. Litig., 288 F.3d 1012, 1018* (7th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003); *see also Fink v. Ricoh Corp.*, 839 A.2d 942, 974 82 (N.J. Super. Ct. 2003) (reviewing extensive differences in state consumer fraud statutes).[47] Accordingly, the need to apply the laws of over fifty jurisdictions precludes any finding of predominance. *See Bridgestone/Firestone*, 288 F.3d at 1015 ("No class action is proper unless all litigants are governed by the same legal rules. Otherwise the class cannot satisfy the commonality and superiority requirements of [Rule 23(b)(3).])"[48]

Plaintiffs seek to avoid the unmanageable task of applying the laws of fifty states by arguing that this Court should apply the law of each defendant's principal place of business. (Pl. Mem. at 38.) However, Judge Young of this Court recently rejected this precise argument,

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[46] As noted above, *see* discussion *supra* note 13, plaintiffs are also attempting to certify their proposed Third-Party Payor classes in connection with their state law consumer protection and civil conspiracy claims. Accordingly, for the reasons discussed herein, the Third-Party Payor classes cannot be certified with respect to plaintiffs' state law claims because individual issues of law predominate.

[47] Defendants have attempted to summarize many of these differences (including issues of standing, reliance, causation, scienter and damages) in the attached Appendix A (Parts 1 & 2), detailing Variations in State Consumer Protection Acts and Appendix B (Parts 1 & 2), detailing Variation in Civil Conspiracy/Fraud Law. It is, of course, impossible to capture all of the variations in state law in a chart, because there may be variations in nuance, *see Lyon v. Caterpillar, Inc.*, 194 F.R.D. 206, 219 (E.D. Pa. 2000) (noting that nuanced variations in state consumer protection statutes made subclassing impossible), as well as state-by-state variations in the application of public policy concerns, *see, e.g., Port. Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 317 (3d Cir. 1999).

[48] *See also Castano*, 84 F.3d at 741 (stating that "[i]n a multi-state class action, variations in state law may swamp any common issues and defeat predominance"); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 276 (D. Mass. 2004) (acknowledging that "federal appellate courts have viewed class actions governed by the law of multiple states with serious skepticism").

holding that Massachusetts' "choice of law rules would select the various states in which consumers' purchases were made" rather than the state where the defendant is located. *In re Relafen*, 221 F.R.D. at 278. As Judge Young noted, to apply the law of the defendant's state "would be at best a 'novelty,' and at worst a violation of constitutional limitations." *Id.* at 277.[49] In actions under state consumer protection statutes, it is the state where the consumer resides that has the most significant relationship to the dispute. *See id.* at 277-78. Likewise, in actions for fraud, the place where the plaintiff received and acted upon the alleged misrepresentation, especially if that is also the plaintiff's residence or place of business, is more significant than the defendant's place of business. *See* Restatement (Second) of Conflict of Laws § 148(2) & cmts. i & j (1971). This result is consistent with other cases in this circuit.[50]

Indeed, plaintiffs' choice of law approach would raise serious constitutional issues. *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("[a] basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction"). These constitutional constraints may not be ignored simply to facilitate certification of a class. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821 (1985). [51]

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[49] Although Judge Young certified a multi-state class, it was limited to a few states with similar laws. The court excluded from the class persons in states with conflicting laws. *See also Relafen,* 221 F.R.D. at 278-87.

[50] *See Reicher v. Berkshire Life Ins. Co.*, 360 F.3d 1, 5-6 (1st Cir. 2004) (refusing to apply Massachusetts' consumer protection statute to claim by a Maryland resident where to do so would undermine Maryland's regulatory scheme with respect to such claims); *Tidemark Bank for Sav. v. Morris*, No. 91-13214-MA, 1993 WL 443936, at *4 (D. Mass. Oct. 21, 1993) (applying law of the state where the plaintiff acted upon the misrepresentation), *aff'd*, 57 F.3d 1061 (1st Cir. 1995); *Computer Sys. Eng'g, Inc. v. Qantel Corp.*, 571 F. Supp. 1365, 1369 (D. Mass. 1983), *aff'd*, 740 F.2d 59 (1st Cir. 1984) ("[t]he place of business of the plaintiff is significant because any financial loss is likely to be of greatest concern to the state having the closest relationship to the person or entity harmed.").

[51] These issues, including the underlying policies and constitutional limitations, are addressed in Defendant GlaxoSmithKline's Individual Mem. In Opp'n to Class Cert., *see supra* note 13.

B. Common Issues of Fact Do Not Predominate as to Part B Drugs

Part B drugs present their own complexities that undermine both predominance and manageability. Reimbursement of drugs under Medicare Part B has been subject to different reimbursement regimes during the Class Period. In 1992, HCFA set the maximum reimbursement under Part B at the lesser of 100 percent of AWP (a term long used in the industry by that time) or estimated acquisition cost. At that time, it was well known to HCFA and the industry that AWP did not represent average acquisition cost. In 1997, Congress rejected HCFA's proposal to reimburse for Part B drugs based on acquisition costs. As a result, from January 1, 1998 through the filing of the complaint, Medicare reimbursed covered drugs at the lower of the actual charge, or 95% of AWP. (Young Decl. ¶¶ 166-68.)

Part B claims are administered by private insurers ("Carriers") pursuant to contracts with the government. The government has invested such Carriers with significant discretion in administering Part B claims, including (at various times) determining whether physician charges were reasonable and adjusting reimbursement for local drugs through Local Medical Review Policies, resulting in wide variability from one carrier to the next as to the actual Medicare reimbursement amount for many drugs. (Young Decl. ¶¶ 169-72.) In addition, in many cases physicians do not base their charges on AWP – they either charge less than the allowed amount or any apparent relationship between their charges and AWP is a coincidence. (*Id.* ¶ 170.) [52] The only way a jury can determine what happened in those instances is to hear testimony from the physicians themselves, a prospect that would require thousands of mini-trials. (Hartman Dep. 274-278 (WFC Ex. 10).) [53]

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[52] *See also* Response of the United States to Defendants' Motion in Limine to Exclude All Evidence Relating to TAP's "Return to Practice" Marketing Activities, *U.S. v. MacKenzie*, No. 01-CR-10350-DPW (D. Mass. Apr. 19, 2004), p. 7, n.3 ("Nothing [in the Medicare Part B regulations] prevented a doctor from billing Medicare at *less* than the published AWP; *indeed, that happened routinely* . . . .") (emphasis added).

[53] Further complicating the necessary analysis is the fact that it was understood and intended that some portion of the drug payment would reimburse physicians for their fees, overhead and other expenses in administering the drugs. (Young Decl. ¶ 162.) Thus, even if there was some consistency as to the AWP component, it would be necessary to look at reimbursement for the bundled service and product, further undermining predominance. *See* discussion *supra* at II.B.2.

Similar difficulties exist with respect to individual Medicare beneficiaries who may be members of the class. Most Medicare beneficiaries, but not all, have some form of insurance for their Medicare co-payment. Depending on whether an individual has one of ten "standardized" plans, a non-standard plan, an employee-sponsored plan, Medicaid, or no coverage, he may be responsible for none, all or a portion of the 20 percent co-payment, a flat co-payment, a deductible, or excess charges. (Young Decl. ¶ 175-77.) The enormous task of attempting to identify which Medicare beneficiaries are members of the proposed class is made even more difficult by the fact that a particular class member's supplemental insurance, if any, will vary over time.[54]

C. None of the Named Plaintiffs Can Represent Medicare Part B Payors

To establish the typicality requirement of Rule 23(a), a class representative's claims must "arise[] from the same event or practice or course of conduct that gives rise to the claims of other class members, and [] his or her claims [must be] based on the same legal theory." *In re American Med. Sys.*, 75 F.3d at 1082; *see also In re Polymedica Corp. Sec. Litig.*, 224 F.R.D. 27, 36 (D. Mass. 2004) (Keeton, Sr. J.). Moreover, "[a] necessary consequence of the typicality requirement is that the representative's interests will be aligned with those of the represented group, and in pursuing his own claims, the named plaintiff will also advance the interests of the class members." *In re American Med. Sys*, 75 F.3d at 1082. Although the presence of a unique defense will not automatically destroy typicality, *see In re Synthroid Mktg. Litig.*, 188 F.R.D. at 291, it may do so when the unique defense will "skew the focus of the litigation" and create "a

[54] In addition, differences in class member knowledge, as discussed above, also preclude a finding of predominance as to the Part B Class. Although plaintiffs will argue that the Medicare statutory scheme renders individual knowledge irrelevant, it will nonetheless be necessary for some class members to demonstrate lack of knowledge to satisfy the elements of deception or reliance under the relevant state law. *See, e.g., Knapp v. Potamkin Motors Corp.*, 602 A.2d 302, 304 (N.J. Super. Ct. 1991) (holding that it was reversible error to instruct jury that plaintiff did not have to prove that he was misled); *Oliveira*, 776 N.E.2d at 163 (holding that plaintiff failed to state a claim under Illinois's statute when he did not allege that he was deceived). Likewise, Part B class members' reliance on a discovery rule or fraudulent concealment to avoid a limitations bar will place their knowledge at issue. *See* discussion *supra* at II.A.

danger that absent class members will suffer if their representative is preoccupied with defenses unique to it." *Alaska v. Suburban Propane Gas Corp.*, 123 F.3d 1317, 1321 (9th Cir. 1997).

While the Medicare Part B Class includes potentially millions of individual Medicare Part B beneficiaries who made co-payments under the program, not one of the named plaintiffs is such an individual. Although the Association plaintiffs claim, in self-serving affidavits submitted in support of plaintiffs' Motion for Class Certification, that their constituent members made co-payments under Medicare Part B, the evidence does not support such allegations. For example, the Executive Director of CCJ, who testified as the 30(b)(6) witness for that Association plaintiff, admitted that she could not state definitively whether any of CCJ's members had, in fact, made a co-payment under Medicare Part B. (Townsend Tr. 179 (WFC Ex. 15).) Moreover, the Association plaintiffs only assert claims for injunctive or declaratory relief and, therefore, cannot adequately represent class members asserting damage claims. *See, e.g.*, *Rosmer v. Pfizer, Inc.*, No. Cv. 9:99-2280-18RB, 2001 U.S. Dist. LEXIS 6678, at *5 (D. S.C. Mar. 30, 2001) ("[T]he fundamental flaw with Plaintiff's representation of the class is the fact that Plaintiff could not himself be eligible for the recovery sought."). Given the fact that approximately half of the state consumer protections statutes only provide a private cause of action to consumers, *see* Appendix A (Parts 1 & 2), the absence of a plaintiff who can adequately represent individual Medicare beneficiaries precludes certification.

This absence of any individual plaintiff who is a Medicare Part B beneficiary is also significant to the typicality analysis under Rule 23(a) because the health and welfare benefit funds who purport to be the class representatives are situated very differently from the absent individual members they purport to represent. As a preliminary matter, with the exception of plaintiff UFCW, none of these proposed class representatives even alleges that it made co-payments under Medicare Part B. *See* AMCC ¶¶ 26-31. Moreover, the evidence indicates that even UFCW does not make Medicare Part B co-payments; rather, it makes what is called payments "secondary" to Medicare. This only occurs in rare situations and UFCW has produced

claim evidence of only three instances where this has happened. (Ryan Tr. (3/16/04) 86-94 (SJY Vol. II.A).) More importantly, even in those rare instances where UFCW pays secondary to Medicare, it does not make payments related to the co-pay owed by the member/Medicare Part B beneficiary. (Ryan Tr. (3/16/04) 99-103, 105-06, 110-111, 113-14 (SJY Vol. II.A).) As a result, plaintiff UFCW will be subject to arguments and defenses that may not be available with respect to the claims of absent class members. These defenses will likely "skew the focus of the litigation" and result in unfairness to the unnamed members of the proposed Medicare Part B class. *Suburban Propane Gas Corp.*, 123 F.3d at 1321. Accordingly, due to the lack of a typical and adequate class representative, the proposed Part B class may not be certified.

IV. A Class Action Is Not a Superior Method for Adjudication of Plaintiffs' Claims

Rule 23(b)(3) also requires plaintiffs to establish that "a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). The superiority test is separate and distinct from the predominance test. *See Haley v. Medtronic, Inc.*, 169 F.R.D. 643, 654 (C.D. Cal. 1996). In determining whether the superiority requirement is met, the Court must consider "the difficulties likely to be encountered in the management of a class action." Fed. R. Civ. P. 23(b)(3)(D).

In conducting this analysis, a court must not be "unmindful of the tremendous administrative burden and management problems created by ill-advised massive class action litigation." *Kendler v. Federated Dep't Stores, Inc.*, 88 F.R.D. 688, 696 (S.D.N.Y. 1981). In particular, Rule 23(b)(3) requires the court to "inquire into how a case would be tried." *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 740, 745 n.18 (5th Cir. 1996) (court must). As explained below, this case is untriable as a class action. It is riddled with practical difficulties and constitutional infirmities that preclude any finding of superiority.

A. Plaintiffs' Vague Trial Plan For Determining Liability Is Unworkable

Plaintiffs' trial plan illustrates, rather than eliminates, the difficulties that will be encountered in the trial of plaintiffs' proposed class action. Plaintiffs propose that the Court try

this matter to a jury on a class-wide basis in two phases: in Phase I plaintiffs will prove the elements of their causes of action "using evidence that is common to all class members," and in Phase II the jury or a Special Master will determine the damages allegedly suffered by each class member. (Plaintiffs' Proposed Two-Phase Trial Plan ("Trial Plan"), at 1.) Plaintiffs' "evidentiary outline demonstrating how this case will be tried as a class action" states that "Dr. Hartman's Declaration establishes and provides a foundation for how this can be accomplished at trial." *Id.*, at 1-2. Dr. Hartman's Declaration, in turn, states that a "formulaic methodology will identify injury, *liability* and damages." (Hartman Decl. (emphasis added) ¶ 37.)

Noticeably absent from plaintiffs' Trial Plan and the "evidentiary outline" is any indication that any class member will offer testimony and be subject to cross-examination during plaintiffs' proposed "trial." Plaintiffs' plan to try individual elements of liability – proximate cause, cause-in-fact and injury – by statistics and sampling raises issues of constitutional proportion. Nor does plaintiffs' "evidentiary outline" mention, much less address, how defendants' affirmative defenses will be adjudicated. In short, plaintiffs' Trial Plan appears to contemplate a "trial" in name only. *See In re Fibreboard Corp.*, 893 F.2d 706, 712 (5th Cir. 1990). ("It is called a trial, but it is not.")

1. Constitutional Principles Require That Defendants Be Allowed to Cross-Examine the Class Representatives and Members at Trial

Defendants have a due process right to confront the class representatives and each class member on questions of fact unique to their claims. A trial plan that provides for a finding of liability without allowing such cross-examination and requiring each class member to prove individualized elements of his causes of action violates due process. *See In re Fibreboard Corp.*, 893 F.2d at 710-12 (vacating on due process grounds a class action trial plan that proposed to determine defendants' liability to 2,990 class members on the basis of evidence concerning 41

plaintiffs); U.S. Const. amend. V.[55] Defendants in a class action cannot be "forced to defend against a fictional composite [plaintiff] without the benefit of deposing or cross-examining the disparate individuals behind the composite creation." *Broussard v. Meineke Disc. Muffler Shops, Inc.*, 155 F.3d 331, 345 (4th Cir. 1998).

2. Causation Will Require a Plaintiff-by-Plaintiff Determination

Similarly, the portion of plaintiffs' proposed Trial Plan entitled "Proximate Cause of Injury" (Trial Plan, at 3) indicates that not a single class member will testify to prove proximate cause, cause-in-fact, and injury. Instead, plaintiffs apparently intend to separate issues of general causation from issues of individual causation and prove only "general causation" in Phase I.

Proof of "general causation," – *i.e.*, whether a defendant's conduct is capable of causing injury – will not significantly advance the litigation or put this Court any closer to a liability determination. *See Cimino v. Raymark Indust., Inc.*, 151 F.3d 297, 313 (5th Cir. 1998) ("causation . . . must be determined as to 'individuals, not groups'"); *In re Fibreboard Corp.*, 893 F.2d 706 at 711-712; *In re "Agent Orange" Prod. Liab. Litig.,"* 818 F.2d 145, 165 (2d Cir. 1987); *In re Paxil Litig.*, 212 F.R.D. 539, 548 (C.D. Cal. 2003). The only causation that matters for purposes of determining a defendant's liability to a class member is whether a defendant's conduct proximately caused and was the cause-in-fact of an individual class member's injury – something that requires inquiry of each plaintiff and cannot be determined on a class-wide basis.[56]

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[55] *See also Goldberg v. Kelly*, 397 U.S. 254 (1970) ("In almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses.").

[56] Moreover, in order for the jury's findings on potentially "common" issues to have any applicability to the claims of absent class members, the jury cannot render a generic liability verdict, but must submit specific findings as to each element of each of plaintiff's causes of action in relation to each act, drug, and time period at issue. *See Blyden v. Mancusi*, 186 F.3d 252, 266, 271 (2d Cir. 1999) (reversing jury verdict because jury verdict form in class action contained general findings of liability that were useless in determining defendants' liability to any class member).

As demonstrated above, no class member can establish liability if it knew – or had the means of knowing – about the spread between ASP and AWP. Because each class member's knowledge must be tried on an individual basis, the Court will be confronted with a multitude of mini-trials. The courts of appeals have routinely held that the risk of "an overwhelming deluge of mini-trials" undermines manageability. *Windham v. American Brands*, 565 F.2d 59, 67 (4th Cir. 1977) (finding that risk of "deluge of mini-trials" on individual issues justifies denial of class certification).[57]

Plaintiffs' proposal to try general causation in one trial and specific causation in numerous mini-trials also raises constitutional issues. The Seventh Amendment entitles parties to have related issues of fact decided by one jury, and prohibits a second jury from reexamining those facts and issues. *See Gasoline Prods. Co. v. Champlin Refining Co.*, 283 U.S. 494, 499-501 (1931); *Castano*, 84 F.3d at 750; U.S. Const. amend. VII. This rule is dictated by the practical concern that if separate juries decide interrelated factual questions, the verdicts rendered by each jury on the same issues could be inconsistent. *See Alabama v. Blue Bird Body Co., Inc.*, 573 F.2d 309, 318 (5th Cir. 1978); *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995). Here plaintiffs' proposal of not merely separate trials on liability and damages, but separate trials on various aspects of liability permitting separate juries to reconsider interrelated issues of fraud, causation and other matters would violate the defendants' constitutional right to a single jury trial on these liability issues.[58]

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[57] *See, e.g., In re LifeUSA Holding Inc.*, 242 F.3d 136, 148 (3d Cir. 2001) (finding certification an abuse of discretion where "attempting to adjudicate plaintiffs' various claims through a class trial" would be "inordinate time consuming and difficult"); *In re American Med. Sys.*, 75 F.3d 1085 ("the economies of scale achieved by class treatment are more than offset by the individualization of numerous issues relevant only to a particular plaintiff"); *Zimmerman,* 800 F.2d at 390 ("The possibility of such individualized determinations would impose an excessive managerial burden upon the district court."); *Nichols v. Mobile Bd. of Realtors, Inc.*, 675 F.2d 671, 679 (5th Cir. 1982) (finding that individual issues justified the district court's decision to decertify a Rule 23(b)(3) class because the "case would degenerate into a series of mini-trials before liability could be established"); *Simer,* 661 F.2d 673 (class certification properly denied where individualized proof "would require a long series of mini-trials and would be an arduous task for the parties as well as the district court").

[58] Plaintiffs' Trial Plan contains a fleeting reference to "Fed. R. Civ. P. 23 (e) (sic)(4) ('When appropriate . . . an action may be brought or maintained as a class action with respect to particular issues[.]')." Trial Plan, at 1.

3. A Defendant's Liability to the Class Representatives and Members Requires Adjudication of All Affirmative Defenses

"Affirmative defenses should be considered in making class certification decisions." *See Waste Mgmt.*, 208 F.3d at 295. At a minimum, each defendant will assert the affirmative defense of statute of limitations for at least part of the proposed class period (which reaches back to 1991). This defense will also turn on what each class member knew and when he, she or it knew it, requiring individual proof that will be different for each class member and contingent upon each member's particular circumstances.

4. Plaintiffs' Proposed Use of Statistical Sampling, Claims Forms, and a Special Master Would Violate Defendants' Constitutional Rights to Due Process and a Fair Trial

Courts have rejected the idea of adjudicating individual issues in a class proceeding "through the use of claim forms, statistical random sampling, depositions, expert opinion and court-appointed special masters." *Arch v. American Tobacco Co.*, 175 F.R.D. 469, 493 (E.D. Pa. 1997). These methods "abrogate the constitutional rights of defendants." *Id.; see also In re Fibreboard Corp.*, 893 F.2d 706, 710-12 (5th Cir. 1990) (concluding that use of illustrative evidence as to individual issues to arrive at a lump sum verdict for the 3,000 class members unlawfully submerged the discreet components of class members' claims in the asbestos manufacturers' defenses). Dr. Hartman explained during his deposition that he intends to "sampl[e] the variety of end users [class members] to see what they knew and the extent to which they were injured . . . ." (Hartman Tr. 162-163; *see also id.* at 221-22, 227-229, 335-36 (WFC Ex. 10).) He then intends to analyze his sample by calculating "averages" that will enable him to ignore the facts of any particular class member. (Hartman Tr. 359-60 (WFC Ex. 10).) Dr. Hartman compared his proposed sampling technique to the polling of voters in the

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Apparently, plaintiffs' position is that if individual issues exist the Court should simply shear the individual issues away from the common issues and in turn certify a class action of common issues. In order to litigate particular issues on a class basis under Rule 23(c)(4), those issues must satisfy the other requirements of Rule 23, however, to achieve certification. *See, e.g., Castano*, 84 F.3d at 745 n.21; *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig. (MTBE)*, 209 F.R.D. 323, 351 (S.D.N.Y. 2002). Plaintiffs have failed to identify *any* such issues.

presidential campaign. (Hartman Tr. 338-39 (WFC Ex. 10).) Defendants' liability to each class member cannot be decided by "sampling" any more than the presidential election can be decided by the Gallup poll.

B. The Necessity of Countless Mini-Trials to Determine Individual Damages Would Render the Proposed Class Action Unmanageable

It is well settled that manageability may be destroyed "solely by the complexity of determining damages." *Piggly Wiggly*, 215 F.R.D. at 531 (citing cases).[59] Here, to calculate a class member's damages in this case, the Court would be required to determine (1) the net price each class member actually paid for each of defendants' products, after accounting for any manufacturer rebates received, and (2) the price that particular class member – under its unique characteristics and contractual arrangements – should have paid for the product at issue under the "expectation" theory of plaintiffs' expert. (Gaier Decl. ¶ 44-46.) Because each third-party payor – whether an Aetna or a union benefit fund – may pay very different amounts for a particular product even on a single day, this analysis will require consideration of each of the hundreds of millions of transactions potentially at issue in this case over the proposed class period that spans more than a decade.

Moreover, there is no formula that could be used to reliably calculate damages in this case on a class-wide basis. As one court has noted, "given the numerous independent factors that go into both the price that should have been paid and the price that was actually paid, [there is no] general formula for calculating damages with precision, amounting to more than speculation, without requiring some degree of inquiry into the individual facts of 52,000 Plaintiffs and

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[59] *See also Sikes*, 281 F.3d at 1365-66; *Broussard*, 155 F.3d at 343; *Lester*, 217 F.R.D. at 354 (where fact-specific, individual determinations of damages would number in the thousands, class presents insurmountable manageability problems); *Church v. General Elec. Co.*, 138 F. Supp. 2d 169, 181-82 (D. Mass. 2001) (Ponsor, J.) (denying class certification where adjudication would require individualized inquiry into extent of damage to each putative class member's property); *Butt v. Allegheny Pepsi-Cola Bottling Co.*, 116 F.R.D. 486, 492 (E.D. Va. 1987) (where fact-specific, individual determinations of damages would number in the thousands, class presents insurmountable manageability problems).

potentially thousands of transactions." *Piggly Wiggly*, 215 F.R.D. at 531;[60] *cf. In re Relafen Antitrust Litig.*, 221 F.R.D. at 282 (rejecting formulaic model for damages set forth by plaintiffs' expert, economist Dr. Raymond S. Hartman). Indeed, even plaintiffs' expert concedes that there are many individual issues that would have to be addressed during the damages phase, and it might be necessary for each class member to testify about its claim. (Hartman Tr. 97, 162, 361-362, 366-67, 515, 520) (WFC Ex. 10).) Under these circumstances, even if liability could be determined on a class-wide basis, the proposed classes would nonetheless be rendered unmanageable by the need to determine damages on an individual basis.

Plaintiffs also assert that a reasonable way to manage damage calculation in this case would be for the defendants to consent to the appointment of a Special Master to determine injury and amount of damage based upon "proofs of claims." This proposal inappropriately attempts to use the class action mechanism to compel defendants to surrender their fundamental rights to a jury determination on all elements of liability. *See Amchem Prods., Inc.*, 521 U.S. at 613 (instructing that the "rules of procedure 'shall not abridge, enlarge or modify any substantive right'") (quoting 28 U.S.C. § 2073(b)).

C. A Class Action is Not a Superior Method of Adjudication For the Sophisticated Entities That Dominate the Proposed Classes

A class action is a superior method only if no reasonable alternative exists. *See Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1234-35 (9th Cir. 1996). Here, plaintiffs' assertion that class certification is necessary to make class members' claims financially viable is belied by the fact that the proposed classes are dominated by large, sophisticated institutions such as Aetna, Cigna, the Blue Cross Blue Shield companies of the various states, and the employee benefit

[60] *See also Gibbs Props. Corp. v. Cigna Corp.*, 196 F.R.D. 430, 441 (M.D. Fla. 2000) (rejecting plaintiffs' proposed damages formula because the court would have to examine each and every class member's underwriting file to determine whether the premiums paid by that class member were excessive given the class member's circumstances and, if so, by how much; *Arch*, 175 F.R.D. at 493 (rejecting plaintiffs' use of a statistical model to determine damages on a class-wide basis); *Wilcox*, 97 F.R.D. at 447 (class-wide proof of injury and damages is not available because plaintiffs "cannot offer a suitable mathematical formula for computing damages").

plans of the nation's largest employers. If plaintiffs' theory is correct, the potential claims of these institutions are enormous. For example, Dr. Hartman has estimated the total alleged overcharges for two drugs to be $158.2 million and $11.9 million respectively, and this covers only the period from 1997 through 2000. (Hartman Decl., Tables 3A and 3B.) The institutional class members have the incentive to pursue their share of these huge sums on their own, and are more than capable of doing so. In fact, many have pursued direct claims on a similar theory in connection with the Lupron litigation. Under these circumstances, a class action is not a superior method for the adjudication of these claims.

V. No Class May Be Certified for Multiple-Source Drugs

In addition to the reasons stated above, no class may be certified with respect to multiple-source drugs because reimbursement for these drugs is not formulaically based on the AWP of the drug. Private reimbursement generally is based on negotiated and highly variable Maximum Allowable Cost or "MAC" lists that may or may not consider AWP as one of many factors. (Young Decl. ¶ 196.)[61] Similarly, reimbursement for multiple-source drugs under Medicare Part B is by regulation based on the median AWP of the class rather than the individual AWP for any drug in the class, *see* 42 C.F.R. 405.517, requiring a case-by-case review of all transactions to determine which drug's AWP happened to be determinative. (Gaier Decl. ¶ 67.) Accordingly, as is shown more fully in the Warrick brief submitted by the Schering Group, plaintiffs cannot establish causation or injury on a class-wide basis for multiple-source drugs, including generic drugs. Thus, no class can be certified with respect to these drugs.

CONCLUSION

For all of the foregoing reasons, plaintiffs' Motion for Class Certification should be DENIED.

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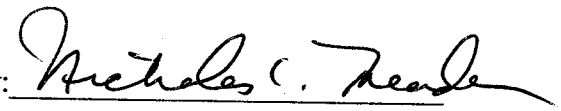
[61] *See also* Hartman Decl. Attachment D, ¶ 37 ("[H]ow TPPs actually define MAC and the extent to which the TPPs strictly enforce MAC are unknown."); Einhorn Tr. 136 (SJY Vol. II.A) (testimony from THWF Rule 30(b)(6) designee that its methodology for setting MACs is not tied to AWP).

Respectfully submitted,

THE TRACK 1 DEFENDANTS

By: 

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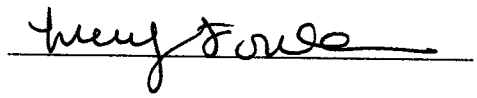
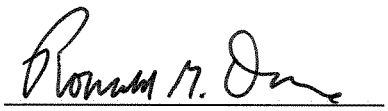
CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by express mail on October 25, 2004.



CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2004, I caused a true and correct copy of the Track 1 Defendants' Memorandum in Opposition to Class Certification [Redacted Version] and the accompanying Declaration of Ronald G. Dove, Jr. to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.



Ronald G. Dove, Jr.